

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
Case No.: 1:19-cv-272-LCB-LPA

MAXWELL KADEL, et al.,)	
)	
Plaintiffs;)	
v.)	
)	
DALE FOLWELL, in his official)	
capacity as State Treasurer of North)	
Carolina, et al,)	
)	
Defendants.)	

Declaration of
STEPHEN B. LEVINE, M.D.
Version of APRIL 28, 2021

SECTION I. CREDENTIALS - KNOWLEDGE, TRAINING, and EXPERIENCE:

1. Education - Academic Appointments - Research Grants: I am a Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine, and also maintain an active private clinical practice. I received my MD from Case Western Reserve University in 1967, and completed a psychiatric residency at the University Hospitals of Cleveland in 1973. I became an Assistant Professor of Psychiatry at Case Western in 1973, and became a Full Professor in 1985. I have been the recipient of the following grants for scientific research and/or program development:

- a. 23 separate pharmaceutical company grants to study various prosexual medications
- b. U.S. National Institute of Health grant for the study of sexual consequences of Systemic Lupus Erythematosus. Co-principal investigator

- c. 5 separate grants from the private Sihler Mental Health Foundation
 - to create the Program for Professionals which evaluated medical and religious leaders accused of sexual offenses
 - to establish a Center for Marital and Sexual Health
 - to create a placebo controlled research study on Clomipramine for Premature ejaculation
 - to create a follow-up study of clergy accused of sexual impropriety
 - to establish a new clinical service for women with breast cancer

2. Medical-Psychiatric Specialty Areas of Focus - Recent Addresses : Since July 1973 my specialties have included psychological problems and conditions relating to sexuality and sexual relations including sexual identity issues, therapies for sexual problems, and the relationship between love and intimate relationships and wider mental health. In 2005, I received the Masters and Johnson Lifetime Achievement Award from the Society of Sex Therapy and Research. I am a Distinguished Life Fellow of the American Psychiatric Association. Over the years I have lectured frequently to professional groups. During the previous two years, these lectures have included:

- a. March 12, 2021-*The Mental Health Professionals 'Role with the Transgendered: Making the Controversies Clear*, given to Grand Rounds at the University Hospitals of Cleveland
- b. May 1, 2021 Psychotherapeutic Approaches to Sexual Problems, an Invited lecture to the American Psychiatric Association Annual Meeting (similar lecture in May 2020)
- c. Seven years of six-hour Continuing Education Courses at the American Psychiatric Association Meetings on Love and Sexuality

d. Grand Rounds at Cleveland Clinic Foundation on Sexuality Education of Psychiatric Residents on June 25, 2020

e. Grand Rounds at Cleveland Clinic Foundation June 2019 *Transgenderism: Beware!* Repeated by invitation at Akron General Hospital and at National meeting of American Association of Behavioral Health in 2019 in Washington, DC

f. Three-hour workshop at Society of Sex Therapy and Research in April 2020 on Therapy for Sexual Problems

g. Workshop on “Lets talk about sex!” at the American Association of Directors of Psychiatric Residency Training in March 2020 in Dallas, Texas

h. Three-hour continuing education seminar with Massachusetts Department of Corrections *Gender Identity Staff* Fall 2019 in Foxboro, Ma

i. Also, I have been a visiting professor at Stanford University and St. Elizabeth's Hospital in DC as well a grand rounds presenter at various departments of psychiatry over many years.

j. I have served as a book and manuscript reviewer for numerous professional publications. I have been the Senior Editor of the first (2003), second (2010) and third (2016) editions of the *Handbook of Clinical Sexuality for Mental Health Professionals*. In addition to five other solo authored books, I authored *Psychotherapeutic Approaches to Sexual Problems*, published in 2020; it has a chapter titled “The Gender Revolution.”

k. While I am a frequent reviewer of submitted papers to the Archives Sexual Behavior, Journal of Sex & Marital Therapy, and Journal of Sexual Medicine.

l. I am an infrequent or occasional reviewer for 25 other journals in various medical specialties and psychological and sociologic journals on topics related to human sexuality.

3. Founder of the Case Western Gender Identity Clinic - former WPATH Chairman of the Standards of Care Committee: I first encountered a patient suffering what we would now call gender dysphoria in July 1973. In 1974, I founded the Case Western Reserve University Gender Identity Clinic, and have served as Co-Director of that clinic since that time. Across the years, our Clinic evaluated and treated hundreds of patients who were experiencing a transgender identity. An occasional child was seen during this era. I was the primary psychiatric caregiver for several dozen of our patients and supervisor of the work of other therapists. I was an early member of the Harry Benjamin International Gender Dysphoria Association (later known as WPATH) and served as the *Chairman of the WPATH Standards of Care Committee* that developed the 5th version of its Standards of Care. In 1993 the Case Western Reserve University Gender Identity Clinic was renamed, moved to a new location, and became independent of Case Western Reserve University. I continue to serve as Co-Director. In 2020, the clinic was renamed the Gender Diversity Clinic.

4. Court Appointed Expert: In 2006, Judge Mark Wolf of the Eastern District of Massachusetts asked me to serve as an independent, court-appointed expert in a litigation involving the treatment of a transgender inmate within the Massachusetts prison system. After providing a six-hour workshop to the mental health professionals in the system, I was retained by the Massachusetts Department of Corrections in 2007 as a consultant on the treatment of transgender inmates. I have been in that role continuously since.

5. Experience as an Expert Witness: I was qualified as an expert and testified concerning the diagnosis, understanding, developmental paths and outcomes, and therapeutic treatment, of transgenderism and gender dysphoria, particularly as it relates to children, in 2019 in the matter of *In the Interest of J.A.D.Y. and J.U.D.Y.*, Case No. DF-15-09887-S, 255th Judicial District,

Dallas County, TX (the “*Younger* litigation”). Before and particularly after that contribution, I have given testimony in:

- a. US District Court, Judge Mark L. Wolf’s witness in Michelle Kosilek vs. Massachusetts Dept of Corrections et al. case (transsexual issue) in Boston 2007
- b. Deposition in the Battista vs. Massachusetts Dept. of Corrections case (transsexual issue) in Cleveland October 2009
- c. Witness for Massachusetts Dept. of Corrections in their defense of a lawsuit brought by prisoner Katheena Soneeya. March 22, 2011 Deposition in Boston and October 2018 in Cleveland and 2019 in Boston.
- d. Witness for State of Florida vs. Reyne Keohane July 2017
- e. Pennsylvania legislative testimony. Written submission and live testimony before a committee of the Pennsylvania legislature. March 2020. (Engaged by Pennsylvania Family Institute.)
- f. In the Interests of the Younger Children. Expert testimony by deposition and at trial in Dallas, TX. (Engaged by Texas counsel Odeneal & Odeneal.) (Dallas Cty. Dist. Ct. 2019)
- g. Doe v. Madison Metropolitan School District. Expert declaration submitted February 19, 2020, rebuttal declaration submitted August 14, 2020.
- h. Hecox v. Idaho. Expert declaration submitted June 4, 2020. (D. Idaho)
- i. In the matter of Rhys & Lynn Crawford (Washington State). 3/30/2021 Tingley v. Washington State.. (W.D. Wa.)
- j. London: Queen (Quincy Bell) vs. Tavistock and Portman Clinics and NHS in High Court of London, Decision handed down on December 1, 2020. I was the only American to submit a report. The Court found that puberty blocking hormones could not be administered to

youth and that for any 16 or 17 year old to obtain hormonal therapy for gender dysphoria they must have court approval for its administration.

k. London 2 : In the High Court of Justice Queen's Bench Division administrative court. The Queen (on the application of) L. and Hampshire County Council. (A matter of education about transgender identities in schools; not yet decided.)

l. Expert in this case Kadal v. Folwell: I have been retained by the defense in this case to serve as an expert witness. My compensation is \$400 per hour and such payments are in advance of any written opinions to avoid conflicts of interest and independent judgment.

7. A more complete review of my professional experience, publications, and awards is provided in my curriculum vitae, a copy of which is attached hereto as Exhibit A.

8. Summary of Issues: In this declaration, I offer information and my expert opinions concerning a number of aspects of the phenomenon of Gender Dysphoria and transgender identity (i.e., Gender Discordance, Gender Incongruity), as well as a discussion of competing views among mental health and other professionals as to the appropriate assessment and therapeutic methods-practices for patients who experience gender dysphoria. At many points in this statement, I provide citations to published, peer-reviewed articles that provide foundational or additional supporting or relevant information. A summary of the key points I discuss in this statement includes:

a. Sex as defined by biology and reproductive function cannot be changed. While hormonal and surgical procedures may enable some individuals to "pass" as the opposite gender during some or all of their lives, such procedures carry with them physical, psychological, and social risks, and no procedures can enable an individual to perform the reproductive role of the opposite sex. (Section II.A.)

b. The diagnosis of “gender dysphoria” encompasses a diverse array of conditions, with widely differing pathways and characteristics depending on age of onset among other things. Data from one population (e.g. adults) cannot be assumed to be applicable to others (e.g. children). (Section II.B.)

c. Among psychiatrists and psychotherapists who practice in the area, there are currently widely varying views concerning both the causes of and appropriate therapeutic response to gender dysphoria. Existing studies do not provide a basis for a reliable scientific conclusion as to which therapeutic responses result in the best long-term outcomes for affected individuals — thus the field remains in an experimental stage. (Sections II.E, II.F.)

d. For example, a majority of children (in several studies, a large majority) who are diagnosed with gender dysphoria “desist”—that is, their gender dysphoria does not persist—by puberty or adulthood. It is not currently known how to distinguish children who will persist from those who will not — thus the majority of patients will do best with no “affirmation” treatments in childhood and we cannot reliably determine which patients would do better with “affirmation” treatments which can involve life-long damage to healthy organs and natural biological processes. (Section IV.) See consistent findings in detailed discussions of the new National Gender Dysphoria Review Guidelines from Sweden, Finland, England, the Cochrane Review, and science articles below.

e. Some recent studies suggest that active affirmation of transgender identity in young children will substantially reduce the number of children naturally outgrowing or “desisting” from transgender identity. This raises ethical and public health concerns that “affirmation” treatments will increase the number of individuals who suffer the multiple long-term

physical, mental, and social limitations that are strongly associated with living life as a transgender person. (Section IV.)

f. Thus, social transition is itself an important intervention with profound implications for the long term mental and physical health of the child. When a mental health professional evaluates a child or adolescent and then recommends social transition, presumably that professional is available to help with interpersonal, familial, and psychological problems that may arise. However, many adolescents transition without mental health assessment and ongoing care, leaving themselves and their families on their own to deal with subsequent problems. (Section IV.)

g. In most cases, parental involvement is necessary for an accurate and thorough diagnosis of a child or adolescent presenting with gender dysphoria or a desire for a transgender identity, as well as for effective psychotherapeutic treatment and support of the young person. (Section V.)

h. The knowledge base concerning the cause and treatment of gender dysphoria available today has been repeatedly characterized in multiple reviews as of “low scientific quality”. (Section VI.) (See detailed analysis below).

i. There are currently no studies that show that affirmation of transgender identity in young children reduces suicide, suicidal ideation, or improves long-term outcomes as compared to other therapeutic approaches. Meanwhile, multiple studies show that adult individuals living transgender lives suffer much *higher* rates of suicide and *negative* physical and mental health conditions than does the general population thus it remains unclear how much benefit, if any, is provided by the experimental treatments required for medical transitioning. (Section VI.)

j. In light of what is known and not known about the impact of affirmation on the incidence of suicide, suicidal ideation, and other indicators of mental and physical health, it is *scientifically baseless and unethical* to assert that a child or adolescent who expresses an interest in a transgender identity will kill him or herself — or is more likely to do so — unless adults and peers affirm that child in a transgender identity. (Section VI.)

k. Putting a child or adolescent on a pathway towards life as a transgender person puts that individual at risk of a wide range of long-term or even life-long harms, including: sterilization (whether chemical or surgical) and associated regret and sense of loss; inability to experience orgasm (for trans women); physical health risks associated with exposure to elevated levels of cross-sex hormones; surgical complications and life-long after-care; alienation of family relationships; inability to form healthy romantic relationships and attract a desirable mate; elevated mental health risks. (Section VII.) In my opinion, putting children through such risks who are very likely to naturally grow out of gender dysphoria into acceptance of their biological sex and gender is an experimental and unethical practice. This is especially true given the affirmation treatments have untested and unproven long-term outcomes.

l. Informed consent is ethically required for potentially life-altering psychological or medical procedures. However, the informed consent process in such complex cases is also complex. In some cases, it may not be possible to obtain meaningful informed consent to place a child on a psychological pathway that carries with it lifetime risks of the serious injuries, harms, and damages (including sterilization, limited sexual response, and social marginalization) that I detail in this report. A child is not competent, of course, to weigh how these potentially devastating life-long risks and issues will impact his or her lifetime happiness. At a minimum, informed consent of parents is essential, although it may not be sufficient. Withholding accurate information

— from patients or parents — on risks and benefits or misrepresenting the current state of research in this controversial field should be viewed as a serious ethics violation and reported to the proper licensing authorities. There is substantial evidence from science publications and also from journalist research that the “affirmation” treatment industry (i.e., often referred to as the Transgender Treatment Industry) is providing misleading information to the public and the legal system. For example, it is not the case that puberty halting hormone treatments are “easily reversed”. (Section VIII.)

m. Research reviews support my opinion that gender affirmation treatments remain experimental and have never been accepted by the relevant scientific community and have no known nor published error rate — meaning the rates of clinical errors as manifested by desistance, increased mental suffering, educational failure, vocational inconstancy, or social isolation have not been established. See, e.g., Haupt, C., Henke, M. et. al., Cochrane Database of Systematic Reviews Review Intervention, Antiandrogen or estradiol treatment or both during hormone therapy in transitioning transgender women, 28 November 2020 ; See, e. g., Swedish Agency for Health Technology Assessment and Assessment of Social Services, SBU Policy Support no 307, 2019 www.sbu.se/en • registrator@sbu.se Contact SBU: Jan Adolfsson, Medical Advisor, Project Manager, jan.adolfsson@sbu.se, English Proofreading: Project group and Jan Adolfsson, SBU [*“No relevant randomized controlled (treatment outcome) trials in children and adolescents were found.”*]

Within the last two years, detailed research reviews exposing multiple and serious methodological and ethical flaws in the research of Bränström, and Panchankis and Turban, and other “affirmation” supporters have pinpointed fundamental methodological errors in their papers which claim to support affirmation treatment. These reviews, also support my opinions that gender

affirmation treatments remain experimental and have never been accepted by the relevant scientific community and have no known nor published error rate. See, Kalin N. H. (2020). Reassessing Mental Health Treatment Utilization Reduction in Transgender Individuals After Gender-Affirming Surgeries: A Comment by the Editor on the Process. *The American journal of psychiatry*, 177(8), 764. <https://doi.org/10.1176/appi.ajp.2020.20060803>; Biggs M. (2020). Puberty Blockers and Suicidality in Adolescents Suffering from Gender Dysphoria. *Archives of sexual behavior*, 49(7), 2227–2229. <https://doi.org/10.1007/s10508-020-01743-6>; D'Angelo, R., Syrulnik, E., Ayad, S., Marchiano, L., Kenny, D. T., & Clarke, P. (2020). One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. *Archives of sexual behavior*, 10.1007/s10508-020-01844-2. Advance online publication. <https://doi.org/10.1007/s10508-020-01844-2>;

n. Bases for Expert Opinions and Review-Opinions regarding the Expert Declarations in this case by Drs. Schechter and Brown. I have reviewed dozens of scientific articles, national science reviews and guidelines (England (NICE), Sweden, Finland, Cochrane Review, association positions, the Complaint and Answer in this case, the plaintiff's medical records, and all expert declarations in this case. I have formulated opinions regarding the reports by Drs. Schechter and Brown. In my opinion, Drs Schechter and Brown failed to properly disclose and discuss the ongoing international debates and controversies as to whether Transgender Treatment Industry methods and procedures are unproven, experimental, and potentially more harmful than helpful to vulnerable patients. Similarly, Drs Schechter and Brown failed to properly disclose and discuss the recent and very public exposes documenting significant methodological failures and flaws in trans treatment science. Finally, Drs Schechter and Brown failed to report or discuss the recently published national reviews and research documenting the “weak” and methodologically defective

research foundations of the Transgender Treatment Industry including recent reviews from Great Britain (NICE), Sweden, Finland, the Cochrane Review, the 2020 Carmichael report, the Griffin study, the Zucker study and other important work published within the last 24 months.. [See, e.g. Carmichael P, Butler G, Masic U, et al. Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. medRxiv 2020.12.01.20241653; doi:<https://doi.org/10.1101/2020.12.01.20241653>

<https://www.medrxiv.org/content/10.1101/2020.12.01.20241653v1>

BBC summary: <https://www.bbc.com/news/uk-55282113> journal.pone.0243894. pmid:33529227

], and Devita Singh, Susan J. Bradley and Kenneth J. Zucker, *Frontiers in Psychiatry*, March 2021 [Volume 12 | Article 632784, www.frontiersin.org] and related research discussed in detail below.

SECTION II. BACKGROUND IN THIS FIELD

A. The biological base line of sex

9. Sex is permanently “assigned” at conception by DNA: The sex of a human individual at its core structures the individual’s biological reproductive capabilities—to produce ova and bear children as a mother, or to produce semen and beget children as a father. Sex determination occurs at the instant of conception, depending on whether a sperm’s X or Y chromosome fertilizes the egg. Medical technology can be used to determine a fetus’s sex before birth. It is thus not scientifically correct to talk of doctors “assigning” the sex of a child at birth; almost anyone can accurately and reliably identify the sex of an infant by genital inspection. What the general public may not understand, however, is that every nucleated cell of an individual’s body is chromosomally identifiably male or female—XY or XX. Claims that patients can obtain a “sex change” or a “gender transition” process are misleading and scientifically impossible. In reality, the typical “transgender” Gender Discordant patient has normal healthy sex organs but struggles

with Gender Discordant feelings and perceived identity. Such patients can receive cosmetic surgeries and hormone treatment — but such methods never actually “transition” a patient to “another sex.” In my opinion, these views are generally accepted by the relevant scientific community in the fields of biology, zoology, neonatology, genetics, pediatrics, and psychiatry.

10. The self-reported gender of a child, in contrast, arises in part from how others label the infant: “I love you, son (daughter).” This designation occurs thousands of times in the first two years of life when a child begins to show awareness of the two possibilities. As acceptance of the designated gender corresponding to the child’s sex is the natural outcome in >99% of children everywhere, anomalous gender discordant identity formation begs for understanding. Is it biologically shaped or influenced? Is it biologically determined? Is it the product of how the child was privately regarded and treated? Does it stem from trauma-based rejection of maleness or femaleness, and if so flowing from what trauma? Is it a symptom of another, as of yet unrevealed emotional disturbance? Is it the result of a social contagion process — such as anorexia or bulimia may be, or from Internet involvement with trans websites? The ongoing scientific, clinical, and societal debate over such issues awaits reliable answers; while some offer authoritative opinions on these questions, they are not scientifically proven. In my opinion, these views are generally accepted by the relevant scientific community.

11. Under the influence of hormones secreted by the testes or ovaries, numerous additional sex-specific differences between male and female bodies continuously develop postnatally, culminating in the dramatic maturation of the primary and secondary sex characteristics with puberty. These include differences in hormone levels, height, weight, bone mass, shape and development, musculature, body fat levels and distribution, and hair patterns, as well as physiological differences such as menstruation. These are genetically programmed biological

consequences of sex which also serve to influence the consolidation of gender identity during and after puberty. In my opinion, these views are generally accepted by the relevant scientific community.

12. Despite the increasing ability of hormones and various surgical procedures to reconfigure some male bodies to visually pass as female, or vice versa, the biology of the person remains as defined by his (XY) or her (XX) chromosomes, including cellular, anatomic, and physiologic characteristics and the particular disease vulnerabilities associated with that chromosomally-defined sex. For instance, the XX (genetically female) individual who takes testosterone to stimulate certain male secondary sex characteristics will nevertheless remain unable to produce sperm and father children. Contrary to assertions and hopes that medicine and society can fulfill the aspiration of the trans individual to become “a complete man” or “a complete woman,” this is not biologically attainable. It is possible for some adolescents and adults to pass unnoticed as the opposite gender that they aspire to be—but with limitations, costs, and risks, as I detail later. See, S. Levine (2018), Informed Consent for Transgendered Patients, *J. of Sex and Marital Therapy*, at 6, DOI: 10.1080/0092623X.2018.1518885 (“Informed Consent”); S. Levine (2016), Reflections on the Legal Battles Over Prisoners with Gender Dysphoria, *J. American Academy of Psychiatry and Law* 44, 236 at 238 (“Reflections”). In my opinion, these views are generally accepted by the relevant scientific community.

B. Definition and diagnosis of gender dysphoria

13. Specialists have used a variety of terms over time, with somewhat shifting definitions, to identify and speak about a distressing incongruence between an individual’s sex as determined by their chromosomes and their thousands of genes, and the gender with which they eventually subjectively identify or to which they aspire. Today’s American Psychiatric

Association's *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5) employs the term Gender Dysphoria and defines it with separate sets of criteria for adolescents and adults on the one hand, and children on the other. It is important to note that the DSM is not a reliable-valid scientific journal publication. The DSM began as an attempt to create a dictionary for psychiatry. The process by which DSM classifications are created involves voting by committee — this is not a reliable-valid scientific process. The committees' recommendations are approved or rejected by superordinate committees. DSM content is largely decided by consensus-seeking methodologies — such as “voting” by small committees of advocates and activist practitioners whose judgment may suffer from significant financial conflicts of interest — as appears to be the case with all three of the plaintiff's experts in this case. The limitations of the DSM methodology are well known in the relevant scientific community. See, e.g., Lee, C., *The NIMH Withdraws Support for DSM-5: The latest development is a humiliating blow to the APA*. Psychology Today News Blog at <https://www.psychologytoday.com/us/blog/side-effects/201305/the-nimh-withdraws-support-dsm-5> [“Just two weeks before DSM-5 is due to appear, the National Institute of Mental Health, the world's largest funding agency for research into mental health, has indicated that it is withdrawing support for the APA's manual. In a humiliating blow to the American Psychiatric Association, Thomas R. Insel, M.D., Director of the NIMH, made clear the agency would no longer fund research projects that rely exclusively on DSM criteria. Henceforth, the NIMH, which had thrown its weight and funding behind earlier editions of the manual, would be “re-orienting its research away from DSM categories.”] In my opinion, these views are generally accepted by the relevant scientific community.

14. There are at least five distinct pathways to gender dysphoria: early childhood onset; onset near or after puberty with no prior cross gender patterns; onset after homosexual lifestyle;

adult onset after years of heterosexual transvestism; and onset in later adulthood with few or no prior indications of cross-gender tendencies or identity. The early childhood onset pathway and the more recently observed onset around puberty pathway are relevant to this matter. Whereas, the onset of cross-gender identifications in the preschool years suggests temperamental and intrafamilial shaping forces, the post pubertal onset of what is now commonly referred to a rapid onset gender dysphoria seems to be heavily influenced by social forces. These derive primarily from the Internet and educational environments. The vulnerability to such social contagion may stem from conspicuous or subtle mental health problems or the child's misunderstanding of the normality of early pubertal discomfort with one's body, previous peer relationships, and despair about future gender-based social roles. The newly acquired trans identity is often passionately held as it explains away past and current unhappiness and emotional or behavioral problems.

Changing Complexities in Young Gender Dysphoric (GD) Patients

15. The Social Contagion Hypothesis. To avoid the methodological error of confirmation bias, clinicians and researchers generate and test alternative hypotheses. It is currently unclear how many new gender discordant patients have been influenced by social contagion processes. During the last 10-15 years, there have been multiple reports from multiple nations reporting a dramatic increase in the number of gender discordant patients as well as a dramatic change in the reported sex ratio of young patients presenting to clinics with trans gender identities. In the 20th century, the biologic male to biologic female ratio was consistently 3-4:1 in most North American and European clinics. Now some clinics are reporting a 7:1 ratio of girls to boys. Biological theories of gender dysphoria (e.g., "immutable", genetic, brain structures, etc.) appear unlikely to explain large, rapid demographic shifts in gender discordant patients. A social contagion - social influence theory has arisen in an attempt to help explain these dramatic demographic changes. In decades

past, gender discordant children and teens typically aspired to become a member of the opposite sex while more recently, patients are increasingly likely to define themselves as “non-binary persons” meaning that they have elements of both sex-genders within them or they have none of these elements. Such teens often report being influenced by trans websites and trans “influencers” on internet sources such as video blogs on YouTube. These online shows reportedly reach millions and teach adolescents to consider their problems, worries, discomforts, and anticipated social roles to be typical experiences of the unfolding of a biologically-determined trans self. In addition to YouTube and other internet sources, patients reportedly have been influenced by school trans awareness training programs teaching the normality of trans current and future lives — without an accurate discussion or depiction of the known risks and benefits.

A multi-disciplinary analysis that includes developmental psychology and the history of psychiatry provides additional support for the socialization hypothesis. Mental health professionals have long experience with adolescent females experiencing social worries that help to create anorexia nervosa, bulimia, and self-harm through cutting, burning, and piercings. Prof. Amanda Rose at the University of Missouri has conducted research to understand why adolescent girls demonstrate heightened susceptibility to a social contagion of psychiatric symptoms. She reports that “teenage girls share symptoms via social contagions because their friendship processes involve “co-rumination”— that is, taking on the emotional pain and concerns of their friends. This is a potential — and as yet uninvestigated hypothesis — as to the reports of “clusters” and “friend groups” of teen girls who are adopting trans identity and “transitioning” together (See, L. Littman (2018), *Parent Reports of Adolescents & Young Adults Perceived to Show Signs of a Rapid Onset of Gender Dysphoria*, PLoS ONE 13(8): e0202330 at 13). Prof. Rose’s investigations note that adolescent girls seem more willing to adopt a friend’s pain and even suspend reality to “get on the

symptom team” of their friends. (See, R. Schwatz-Mette and A. Rose, Co-Rumination Mediates Contagion of Internalizing Symptoms Within Youths’ Friendships, Developmental Psychology 48(5):1355-65, February 2012, DOI: [10.1037/a0027484](https://doi.org/10.1037/a0027484) Further, reliable-valid scientific research is needed to address these complex issues. See also, McCall, B. and Nainggolan, L., Medscape *Transgender Teens: Is the Tide Starting to Turn?* https://www.medscape.com/viewarticle/949842#vp_1 [“The vast majority of youth now presenting with gender dysphoria are adolescents who suddenly express revulsion with their sex from birth, and 70% of them were born female. Many of them have comorbidities such as anxiety, attention deficit hyperactivity disorder, autism spectrum traits, and depression, Malone explains, which need to be considered. This newer presentation — which has been termed late-, adolescent-, or rapid-onset gender dysphoria — has now been seen in every gender clinic in the western world, and there has been a huge surge in the number of cases. One recent US survey found a 4000% increase (over 40-fold) since 2006, and there have been similar large increases reported in Finland, Norway, the Netherlands, Canada, and Australia. The London GIDS clinic reported a 30-fold increase in referrals over the past decade – and again they were primarily adolescent girls who said they now identify as boys.

It should be noted that rapid, unpredicted changes in the demographics of trans patients (i.e., from chronically discordant, early onset males to rapid onset adolescent females) calls into question the usefulness and accuracy of predictions emanating from research conducted on previous, demographically and clinically different patient groups. This again highlights the complex, little known, and experimental nature of trans phenomenon as well as the experimental treatment methods of the current Transgender Treatment Industry. See, rapid and unpredicted demographic changes: [A US survey found a 4000% increase (over 40-fold) since 2006]

"National College Health Assessment: ACHA-NCHA [s://www.acha.org/NCHA/ACHA-NCHA_Data/Publications_and_Reports/NCHA/Data/Publications_and_Reports.aspx?hkey=d5fb767c-d15d-4efc-8c41-3546d92032c5](https://www.acha.org/NCHA/ACHA-NCHA_Data/Publications_and_Reports/NCHA/Data/Publications_and_Reports.aspx?hkey=d5fb767c-d15d-4efc-8c41-3546d92032c5) ; similar large increases have been reported in Finland: Kaltiala-Heino, Riittakerttu, Hannah Bergman, Marja Työläjäarvi, and Louise Frisen. "Gender Dysphoria in Adolescence: Current Perspectives." *Adolescent Health, Medicine and Therapeutics* Volume 9 (March 2018): 31–41. <https://doi.org/10.2147/AHMT.S135432> ; and in Norway ; and in the Netherlands: de Vries, Annelou L.C. de. "Challenges in Timing Puberty Suppression for Gender-Nonconforming Adolescents." *Pediatrics* 146, no. 4 (October 2020): e2020010611. <https://doi.org/10.1542/peds.2020-010611>. ; and in Canada: Zucker, Kenneth J. "Adolescents with Gender Dysphoria: Reflections on Some Contemporary Clinical and Research Issues." *Archives of Sexual Behavior* 48, no. 7 (October 2019): 1983–92. <https://doi.org/10.1007/s10508-019-01518-8>, and others.

16. Gender dysphoria has very different characteristics depending on age and sex at onset. Young children who are living a transgender identity commonly suffer materially fewer symptoms of concurrent mental distress than do older patients. (See, K. Zucker (2018), The Myth of Persistence: Response to "A Critical Commentary on Follow-Up Studies & 'Desistance' Theories about Transgender & Gender Non-Conforming Children" by Temple Newhook et al., *Int'l J. of Transgenderism* at 10, DOI: 10.1080/15532739.2018.1468293 ("Myth of Persistence"). The developmental and mental health patterns for each of these groups are sufficiently different that data developed in connection with one of these populations cannot be assumed to be applicable to another.

17. The criteria used in DSM-5 to identify Gender Dysphoria ("Gender Incongruence" is another term used) include a number of signs of discomfort with one's natal sex and vary

somewhat depending on the age of the patient, but in all cases require “clinically significant distress or impairment in important areas of functioning” such as social, school, or occupational settings. When these criteria in children, (or adolescents, or adults) are not met, two other diagnoses may be given. These are: Other Specified Gender Dysphoria and Unspecified Gender Dysphoria. Specialists sometimes refer to children who do not meet criteria as being “subthreshold.”

18. In a complex, experimental, and little understood field such as transgender medicine, generating and exploring alternative hypotheses is essential to our efforts to help alleviate the tragic suffering of our patients. One such alternative is to teach coping and resilience skills to gender discordant children. Such training could include a realization that a wide range of behaviors are available within their biologically concordant gender roles. Acquiring a broader perspective on the patient’s natal sex roles might be a better solution for some than permanent damage to healthy sex organs via hormone and surgical “transitioning” procedures. Children who conclude that they are transgender are often unaware of a vast array of adaptive possibilities for how to live life as a man or a woman—possibilities that become increasingly apparent over time to both males and females. A boy or a girl who claims or expresses interest in pursuing a transgender identity often does so based on stereotypical notions of femaleness and maleness that are based on constrictive notions of what men and women can be. See, S. Levine (2017), Ethical Concerns About Emerging Treatment Paradigms for Gender Dysphoria, *J. of Sex & Marital Therapy* at 7, DOI: 10.1080/0092623X.2017.1309482 (“Ethical Concerns”). A young child’s, even an adolescent’s, understanding of this topic is quite limited. Nor do they have the perspective that discomfort with the body and perceived social role is not new to civilization; what is new is the option to become a trans person.

With most complex behavioral problems of child and adolescents, patients and families receive psychiatric attention that includes a thorough developmental history from parents, prolonged interviews with the patient, and a therapeutic approach which involves to some extent the parents, the patient, and the three together with or without medication assistance. Tragically, in too many gender clinics, young patients are not treated with the standard of care, complex, multi-disciplinary, evidence-based approach. Children are too often quickly referred to gender “specialists” — which generally means therapists who deeply believe (based on clinical-political ideology and not the relevant science) that every young person who is questioning his or her gender identity or declaring a trans identity should be quickly affirmed and supported in their atypical identity. Moreover, the ideological fashions of these therapists and the organizations that support them have effectively convinced many — contrary to the relevant science — that any other approach to these youth is dangerous, harmful, and might even lead to suicide. Other evidence-based, more methodologically sound approaches such as the generation and testing of alternative hypotheses as required by proper health care standards — are denigrated and ideologically labeled “conversion therapy.”

The ideologically based indoctrination efforts to ban evidence based alternative treatments as “conversion therapy” can have harmful effects on our vulnerable patients. For example, many traditional therapists claim to not know how to take care of these gender discordant patients, as though they are not children who are suffering. This rationalization may only be a reflection of the fear of being attacked for performing dreaded, and now in some locations, illegal, “conversion therapy”. In this way, qualified mental health professionals have failed to develop a robust experience with alternative ways of investigating patients’ and their families’ lives as they do with all other child and adolescent psychiatric problems. [The recently released National Guidelines

for Gender Dysphoria patients from Sweden and Finland do appear to be moving towards a much greater emphasis on alternative methods including psychosocial support, therapy, and long-term psycho-social evaluations — perhaps for years — prior to engaging in any “affirmation” medical interventions (hormones or surgery) See, e.g. “Finland Issues Strict Guidelines for Treating Gender Dysphoria” at <https://genderreport.ca/finland-strict-guidelines-for-treating-gender-dysphoria/> [“Western countries around the world are grappling with how to treat the exponentially growing number of children and adolescents being referred to gender clinics for puberty blockers, cross-sex hormones and gender-affirming surgery. Finland recently issued very strict clinical guidelines for the treatment of children with gender dysphoria including: ... clear differentiation in treatment guidelines between early-onset childhood gender dysphoria and adolescent-onset gender dysphoria...the guidelines acknowledge and recognize that identity exploration is a natural phase of adolescence and restrict medical interventions until “identity and personality development appear to be stable”....There is a *prioritization of psychotherapeutic non-invasive interventions* as the first course of action “due to variations in gender identity in minors”.... A *requirement* that there be “*no contraindications*” *prior to initiation of puberty blocker or cross-sex hormone interventions*... [such contraindications should include the presence of psychiatric illnesses such as depression, anxiety, or autistic conditions. Such disorders are reportedly present in over 50% of all gender discordant patients].... and no surgical interventions are allowed for children under the age of 18.” ; See also, a Swedish National Investigative Report regarding cases of gender incongruence in children and young people, Article number 2021-3-7302 Published www.socialstyrelsen.se, March 2021. [Since our initial investigative report was published in 2015, the number of young people referred for investigation has increased sharply, both in Sweden and internationally. ... The reasons for the increase are not yet clear.]

Such external pressures on providers should not be underestimated. Leaders in the field of gender dysphoria have been attacked, dissenters have been fired, and reputations have been sullied by activists who believe they know best how other people's children should be treated. The fact that science has not yet established the ideal treatment approaches to the diversity of situations does not seem to matter to these passionate persons.

19. Confirmation bias is a hazardous cognitive error that occurs throughout all of medicine and science. Confirmation bias is the methodologically defective tendency to process information by only looking for, and interpreting, evidence consistent with existing beliefs, favorite theories, and pre-conceived notions. This bias is a serious and potentially dangerous methodological error that leads a person or a field to ignore information that is contrary to what is common, fashionable, or has been taught to be the popular or "politically correct" theory of the day. It is often associated with a weak understanding of how science establishes the legitimacy of a therapy. Confirmation bias is often associated with the belief that because a therapeutic approach has been long employed or supported by powerful forces, adequate reliable-valid science must have previously established the popular approach. Both of the essential concepts of "gender affirmative treatment" and "conversion therapy" are based on such a misunderstanding.

20. The expected initial evaluation of a trans person typically begins with the patient who tells the evaluator, "I am trans." The patient relates his or her symptoms of discomfort which may or may not fulfill DSM-5 criteria for Gender Dysphoria. Ideally a developmental history is taken from the parents and the patient to consider what is known as a differential diagnostic process to determine what other conditions may underlie these symptoms. The extent to which this latter process is undertaken depends upon the therapists *beliefs* about the origin of trans identities and the long term effectiveness of affirmative responses. To the extent that life-changing affirmative

treatment programs are *believed* to be already scientifically well established, the differential diagnosis process tends to be glibly superficial. The patient is typically pleased with the rapid affirmation recommendation, although the parents are often horrified by the failure to consider previous struggles the child and family have undergone. Alternative treatment approaches or hypotheses are given short shrift (i.e., confirmation bias). When one grasps the fact that the scientific process underlying affirmation is woefully inadequate “weak evidence” based on often defective research, one can begin to see that confirmation bias can create an unethical process that places patient futures in jeopardy.

C. The inequitable impact of gender dysphoria on minority and vulnerable groups

21.. In considering the appropriate response to gender dysphoria, it is important to know that certain groups of children have an increased prevalence and incidence of trans identities. These include: children of color, children with mental developmental disabilities, including children on the autistic spectrum (at a rate more than 7x the general population), children residing in foster care homes, adopted children (at a rate more than 3x the general population), children with a prior history of psychiatric illness, and more recently adolescent girls (in a large recent study, at a rate more than 2x that of boys). (G. Rider at 4; See, G. Rider et al. (2018), *Health and Care Utilization of Transgender/Gender Non-Conforming Youth: A Population Based Study*, Pediatrics at 4, DOI: 10.1542/peds.2017-1683. (In a large sample, non-white youth made up 41% of the set who claimed a transgender or gender-nonconforming identity, but only 29% of the set who had a gender identity consistent with their sex.) See, D. Shumer & A. Tishelman (2015), *The Role of Assent in the Treatment of Transgender Adolescents*, Int. J. Transgenderism at 1, DOI: 10.1080/15532739.2015.1075929; See also, D. Shumer et al. (2016), *Evaluation of Asperger Syndrome in Youth Presenting to a Gender Dysphoria Clinic*, LGBT Health, 3(5) 387 at 387 ; See

also, Shumer et al. (2017), Overrepresentation of Adopted Adolescents at a Hospital-Based Gender Dysphoria Clinic, *Transgender Health*, Vol. 2(1) 76 at 77 ; See also, L. Edwards-Leeper et al. (2017), Psychological Profile of the First Sample of Transgender Youth Presenting for Medical Intervention in a U.S. Pediatric Gender Center, *Psychology of Sexual Orientation and Gender Diversity*, 4(3) 374 at 375 ("Psychological Profile") ; See, also R. Kaltiala-Heino et al. (2015), *Two Years of Gender Identity Service for Minors: Overrepresentation of Natal Girls with Severe Problems in Adolescent Development*, *Child and Adolescent Psychiatry & Mental Health*, 9(9) 1 at 5. In the 2015 Finland gender identity service statistics, 75% of adolescents assessed "had been or were currently undergoing child and adolescent *psychiatric treatment* for reasons other than gender dysphoria."); these data are consistent with Littman's research. See, L. Littman (2018), *Parent Reports of Adolescents & Young Adults Perceived to Show Signs of a Rapid Onset of Gender Dysphoria*, *PLoS ONE* 13(8): e0202330 at 13 (Parental survey concerning adolescents exhibiting Rapid Onset Gender Dysphoria reported that 62.5% of gender dysphoric adolescents had "a psychiatric disorder or neurodevelopmental disability preceding the onset of gender dysphoria."). Properly protecting vulnerable, marginalized patients from experimental, potentially dangerous treatments should be an essential concern to trans gender treatment industry but has not been.

D. Three competing conceptual models of gender dysphoria and transgender identity

22. Discussions about appropriate responses by mental health professionals ("MHPs") to actual or sub-threshold gender dysphoria are complicated by the fact that various speakers and advocates (or a single speaker at different times) view transgenderism through at least three very different paradigms, often without being aware of, or at least without acknowledging, the

distinctions. I attempt to summarize these three as though they are equally valid. I do not actually consider this to be true.

23. Gender dysphoria is conceptualized and described by some professionals and laypersons as though it were a serious, physical medical illness that causes suffering, comparable, for example, to prostate cancer, a disease that is curable before it spreads. Within this paradigm, whatever is causing distress associated with gender dysphoria—whether secondary sex characteristics such as facial hair, nose and jaw shape, presence or absence of breasts, or the primary anatomical sex organs of testes, ovaries, penis, or vagina—should be removed to alleviate the illness. The promise of these interventions is the cure of the gender dysphoria. The underlying assumption is that all types of gender dysphoria have their ultimate origin in “brain structures”, often determined embryonically. Although numerous studies have been undertaken to attempt to demonstrate a distinctive physical “brain structure” associated with transgender identity, as of yet there is no credible, reliable-valid scientific evidence that these patients have any defining abnormality in brain structure that precedes the onset of gender dysphoria. See, Mueller, De Cuypere & T’Sjoen. Transgender research in the 21st century: A selective critical review from a neurocognitive perspective. *American Journal of Psychiatry* 174: 12, 2017.

It should be noted that gender dysphoria is *a psychiatric rather than a medical diagnosis*. Since its inception in DSM-III, it has always and only been specified in the psychiatric DSM manuals. Notably, *gender dysphoria is the only psychiatric condition to be treated by surgery*, even though no endocrine or surgical intervention package corrects any identified biological abnormality (cf body integrity identity disorder (BIID) (See, Levine, *Reflections*, at 240.) In my opinion, the “affirmation” treatment protocols using endocrine and surgical “treatments” to change a psychiatric condition are not accepted by the relevant scientific community, are supported by

only “weak evidence” from methodologically defective research studies, and have no known, nor published error rates. Actual attempts at publishing error rates has come under the concept of “regrets” focused only on patient injuries and misery following genital re-assignment surgery. There is much more to the human experience of trans patients regrets over time than the questionable, methodologically defective claims quoted by some of 2%. For example, in the Bränström, et.al., study, an enormous part of the sample was “lost” and never followed up. The authors failed to explore available data to see how many of these patients have de-transitioned, died via suicide, etc. One has to wonder why the suicide rate is reportedly so very high for patients who received trans genital surgery. In sum, these “treatments” remain experimental and poorly studied and we’ll need much more and much higher quality scientific research before we will know if such “treatments” are actually helping or injuring patients. It is essential to note that hormonal and surgical treatments for gender discordant patients have been increasingly done over a 50 year period and yet no reliable-valid protocols for evaluation or treatment have been properly researched, nor generally accepted by the relevant scientific community, nor published with methodologically sound error rates. For decades, vulnerable patients struggling with gender identity issues have deserved better, more effective, less experimental, less hazardous, less ideologically tainted, and properly researched treatments — they are still waiting.

24. Gender dysphoria can be effectively and alternatively conceptualized in developmental terms, as an adaptation to a psychological problem that was first manifested as a failure to establish a comfortable conventional sense of self in early childhood. This paradigm starts from the premise that all human lives are influenced by past processes and events. Trans lives are not exceptions to this axiom. (Levine, *Reflections*, at 238.) MHPs who think of gender dysphoria through this paradigm may work both to identify and address causes of the basic problem of the deeply

uncomfortable self, and also to ameliorate suffering when the underlying problem cannot be solved. They work with the patient and (ideally) family to inquire what forces may have led to the trans person repudiating the gender associated with his sex. The developmental paradigm is mindful of temperamental, parental bonding, psychological, sexual, and physical trauma influences, and the fact that young children work out their psychological issues through fantasy and play.

The developmental paradigm recognizes that, with the important exception of genetic sex, essentially all aspects of an individual's identity evolve—often markedly—across the individual's lifetime. This includes gender. While some advocates assert that a transgender identity is biologically caused, fixed from early life, and eternally present in an unchanging manner, this is not supported by science. In contrast, this paradigm points to the sudden enormous increase in incidence of child and adolescent gender dysphoria over the last twenty years in North America and Europe. This points to sociological-psychological processes rather than a biological one. From the beginning of epidemiological research into this arena, there have always been some countries, Poland and Australia, for example, where the sex ratios were reversed as compared to North America and Europe. This, too, points to the powerful effect of cultural influences. See, Levine, *Ethical Concerns*, at 8 (citing M. Aitken, T. D. Steensma, et al. (2015), Evidence for an Altered Sex Ratio in Clinic-Referred Adolescents with Gender Dysphoria, *J. of Sexual Medicine* J. 12(3) 756 at 756-63).

25. In recent years, for adolescent patients, intense involvement with online transgender communities and virtual friends who have never been seen in person is reportedly the rule rather than the exception. The developmental paradigm does not preclude external social influences.

26. The third paradigm through which gender dysphoria is alternatively conceptualized is political (not scientific) — from a sexual minority rights perspective. Under this paradigm, any response other than medical and societal affirmation and implementation of a patient’s claim to “be” the opposite gender or a non-binary person is a violation of the individual’s civil right to self-expression. Any effort to ask “why” questions about the patient’s condition, or to address underlying causes, is viewed as a violation of autonomy and civil rights. In the last few years, this paradigm has been successful in influencing public policy, the education of pediatricians, endocrinologists, and many mental health professionals, and local ordinances prohibiting “conversion therapy.” Activists, legal professionals, and politicians should note that this *political* hypothesis — as powerful as it has become — has never been *scientifically* validated and might, in the end, be far damaging than helpful to suffering, vulnerable gender discordant patients.

E. Competing models of therapy

27. Because of the complexity of the human psyche and the avoidance of running controlled experiments in this area, substantial disagreements among professionals about the causes of psychological disorders, and about the appropriate therapeutic responses, are not unusual. When we add to this the very different paradigms for understanding transgender phenomena, it is not surprising that such disagreements also exist with regard to appropriate therapies for patients experiencing gender-related distress. I summarize below the leading approaches, and offer certain observations and opinions concerning them.

The “watchful waiting” therapy model

28. I review below the uniform finding of follow-up studies that the large majority of children who present with gender dysphoria will desist from desiring a transgender identity by adulthood if left untreated. (See *infra* ¶ 60.)

29. When a pre-adolescent child presents with gender dysphoria, a “watchful waiting” approach avoids hormonal treatments to allow for the developmental nature of gender identity in children to naturally resolve—that is, take its course from forces within and surrounding the child. Watchful waiting has two versions:

- a. (Model 1 of watchful waiting) Treating any other psychological co-morbidities—that is, other mental illnesses as defined by the DSM-5—that the child may exhibit (separation anxiety, bedwetting, attention deficit disorder, obsessive-compulsive disorder, depression) without a focus on gender
- b. (Model 2 of watchful waiting) No treatment at all for anything, but a regular follow-up appointment. This might be labeled a “hands off” approach

The psychotherapy model: Alleviate distress by identifying and addressing causes

30. One of the foundational principles of psychotherapy has long been to work with a patient to identify the causes of observed psychological distress and then to address those causes as a means of alleviating the distress. The National Institute of Mental Health has promulgated the idea that 75% of adult psychopathology has its origins in childhood experience.

31. Many experienced practitioners in the field of gender dysphoria, including myself, have believed that it makes sense to employ these long-standing tools of psychotherapy for patients suffering gender dysphoria, asking the question as to what factors in the patient’s life are the determinants of the patient’s repudiation of his or her natal sex. (Levine, *Ethical Concerns*, at 8.) I and others have reported success in alleviating distress in this way for at least some patients, whether or not the patient’s sense of discomfort or incongruence with his or her natal sex entirely disappeared. Relieving accompanying psychological co-morbidities leaves the patient freer to consider the pros and cons of transition as he or she matures.

32. Among other things, the psychotherapist who is applying traditional methods of psychotherapy may help—for example—the male patient appreciate the wide range of masculine emotional and behavioral patterns as he grows older. He may discuss with his patient, for example, that one does not have to become a “woman” in order to be kind, compassionate, caring, noncompetitive, and devoted to others’ feelings and needs. Many biologically male trans individuals, from childhood to older ages, speak of their perceptions of femaleness as enabling them to discuss their feelings openly, whereas they perceive boys and men to be constrained from emotional expression within the family and larger culture. Men, of course, can be emotionally expressive, just as they can wear pink. Converse examples can be given for girls and women. These types of ideas regularly arise during psychotherapies.

33. Many gender-nonconforming children and adolescents in recent years derive from minority and vulnerable groups who have reasons to feel isolated and have an uncomfortable sense of self. A trans identity may be a hopeful attempt to redefine the self in a manner that increases their comfort and decreases their anxiety. The clinician who uses traditional methods of psychotherapy may not focus on their gender identity, but instead work to help them to address the actual sources of their discomfort. Success in this effort may remove or reduce the desire for a redefined identity. This often involves a focus on disruptions in their attachment to parents in vulnerable children, for instance, those in the foster care system. See, S. Levine (2017), *Transitioning Back to Maleness*, Arch of Sexual Behavior at 7, DOI: 10.1007/s10508-017-1136-9) (“*Transitioning*”).

34. Because “watchful waiting” can include treatment of accompanying psychological comorbidities, and the psychotherapist who hopes to relieve gender dysphoria may focus on potentially causal sources of psychological distress rather than on the gender dysphoria itself, there

is no sharp line between “watchful waiting” and the psychotherapy model in the case of prepubescent children.

35. To my knowledge, there is no credible, reliable-valid scientific evidence beyond anecdotal reports that psychotherapy can enable a return to male identification for genetically male boys, adolescents, and men, or return to female identification for genetically female girls, adolescents and women. *Controlled studies have never been attempted.* On the other hand, anecdotal case report evidence of such outcomes does exist; I and other clinicians have witnessed reinvestment in the patient’s biological sex in some individual patients who are undergoing psychotherapy. The Internet contains many such reports, and I published a paper recently on a patient who sought my therapeutic assistance to reclaim his male gender identity after 30 years living as a woman and is in fact living as a man today. (Levine, *Transitioning*, at 1.) I have seen children desist even before puberty in response to thoughtful parental interactions and a few meetings of the child with a therapist. Recently, a paper reviewing the phenomenon of de-transition has been published in which the authors claims to have identified *60,000 case reports world wide* on the Internet. See Expósito-Campos P. A Typology of Gender Detransition and Its Implications for Healthcare Providers. *J Sex Marital Ther.* 2021;47(3):270-280. doi: 10.1080/0092623X.2020.1869126. Epub 2021 Jan 10. PMID: 33427094.

The affirmation therapy model

36. While it is widely agreed that the therapist should not directly challenge a claimed transgender identity in a child, some advocates and practitioners go much further, and promote and recommend that any expression of transgender identity should be immediately accepted as decisive, and thoroughly affirmed by means of consistent use of clothing, toys, pronouns, etc. associated with transgender identity. These advocates treat any question about the causes of the

child's transgender identification as inappropriate, and assume that observed psychological co-morbidities in the children or their families are unrelated or will get better with transition, and need not be addressed by the MHP who is providing supportive guidance concerning the child's gender identity.

37. Some advocates, indeed, assert that unquestioning affirmation of any claim of transgender identity in children is essential, and that the child will otherwise face a high risk of suicide or severe psychological damage. I address claims about suicide and health outcomes in Section VI below.

38. Some advocates also assert that this "affirmation therapy" model is accepted and agreed with by the overwhelming majority of mental health professionals. However, one respected academic in the field has recently written that, on the contrary, "almost all clinics and professional associations in the world" do not use "gender affirmation" for prepubescent children and instead "delay any transitions after the onset of puberty." See, J. Cantor (2019), Transgender and Gender Diverse Children and Adolescents: Fact-Checking of AAP Policy, *J. of Sex & Marital Therapy* at 1, DOI: 10.1080.0092623X.2019.1698481.

39. Even the Standards of Care published by WPATH, an organization which in general leans strongly towards affirmation in the case of adults, does not specify affirmation of transgender identity as the indicated therapeutic response for young children, but — given that the majority of such children naturally grow out of the problem — rather calls for a careful process of discernment and decision specific to each child, by the family in consultation with the mental health professional.

40. Further, the DSM-5 added—for both children and adolescents—a requirement that a sense of incongruence between biological and felt gender must last at least six months as

a precondition for a diagnosis of gender dysphoria, precisely because of the risk of “transitory” symptoms and “hasty” diagnosis that might lead to “inappropriate” treatments. See, K. Zucker (2015), *The DSM-5 Diagnostic Criteria for Gender Dysphoria*, in C. Trombetta et al. (eds.), *Management of Gender Dysphoria: Multidisciplinary Approach*, DOI 10.1007/978-88-470-5696-1_4 (Springer-Verlag Italia 2015).

41. I do not know what proportion of practitioners are using which model. However, in my opinion, in the case of young children, prompt and thorough affirmation of a transgender identity disregards the principles of child development and family dynamics, and is not supported by credible, reliable-valid scientific evidence. Rather, the MHP must focus attention on the child’s underlying internal and familial issues. Ongoing relationships between the MHP and the parents and the MHP and the child are vital to help the parents, child, other family members, and the MHP to understand over time the issues that need to be dealt with over time by each of them.

42. Likewise, since the child’s sense of gender develops in interaction with his parents and their own gender roles and relationships, the responsible MHP will almost certainly need to delve into family and marital dynamics.

F. Patients Differ Widely and Must Be Considered Individually.

43. In my opinion, it is not possible to make a single, categorical statement about the proper treatment of children presenting with gender dysphoria or other gender-related issues. There is no single pathway of development and outcomes governing transgender identity, nor one that predominates over the large majority of cases. Instead, as individuals grow up and age, depending on their differing psychological, social, familial, and life experiences, their outcomes differ widely. I can, however, categorically opine that unproven, experimental affirmation “treatments” should not be used on uninformed or misinformed patients and families.

44. As to causes in children, details about the onset of gender dysphoria may be found in an understanding of family relationship dynamics. In particular, the relationship between the parents and each of the parents and the child, and each of the siblings and the child should be well known by the MHP. Further, a disturbingly large proportion of children who seek professional care in connection with gender issues have *a wider history of psychiatric co-morbidities*. See Becerra-Culqui TA, Liu Y, Nash R, Cromwell L, Flanders WD, Getahun D, Giammattei SV, Hunkeler EM, Lash TL, Millman A, Quinn VP, Robinson B, Roblin D, Sandberg DE, Silverberg MJ, Tangpricha V, Goodman M. Mental Health of Transgender and Gender Nonconforming Youth Compared With Their Peers. *Pediatrics*. 2018 May;141(5):e20173845. doi: 10.1542/peds.2017-3845. Epub 2018 Apr 16. PMID: 29661941; PMCID: PMC5914494. A 2017 study from the Boston Children's Hospital Gender Management Service program reported that: "Consistent with the data reported from other sites, this investigation documented that 43.3% of patients presenting for services had significant psychiatric history, with 37.1% having been prescribed psychotropic medications, 20.6% with a history of self-injurious behavior, 9.3% with a prior psychiatric hospitalization, and 9.3% with a history of suicide attempts." See, Perez-Brumer A, Day JK, Russell ST, Hatzenbuehler ML. Prevalence and Correlates of Suicidal Ideation Among Transgender Youth in California: Findings From a Representative, Population-Based Sample of High School Students. *J Am Acad Child Adolesc Psychiatry*. 2017 Sep;56(9):739-746. doi: 10.1016/j.jaac.2017.06.010. Epub 2017 Jul 5. PMID: 28838578; PMCID: PMC5695881.

L. Edwards-Leeper, *Psychological Profile*.) It seems likely that an even higher proportion will have had prior undiagnosed psychiatric conditions.

G. Understanding the WPATH and its "Standards of Care"

45. In almost any discussion of the diagnosis and care of patients suffering gender dysphoria or exhibiting transgender characteristics, the World Professional Association for Transgender Health (WPATH) and its Standards of Care will be mentioned. Accordingly, I provide some context concerning that private, activist, non-science, organization.

46. I was a member of the Harry Benjamin International Gender Dysphoria Association from 1974 until 2001. From 1997 through 1998, I served as the Chairman of the eight-person International Standards of Care Committee that issued the fifth version of the Standards of Care. I resigned my membership in 2002 due to my regretful conclusion that the organization and its recommendations had become dominated by politics and ideology, rather than by proper, reliable scientific methodologies, as was its mission years earlier. In approximately 2007, the Henry Benjamin International Gender Dysphoria Association changed its name to the World Professional Association for Transgender Health.

47. WPATH is a voluntary membership, activist advocacy organization. Since at least 2002, attendance at its biennial meetings has been open to trans individuals who are *not licensed professionals*. While this ensures taking patients' perceived needs, values, and sensibilities into consideration, it limits the ability for honest, methodologically competent scientific debate. It also means that WPATH can no longer be considered a purely professional or scientific organization.

48. WPATH takes a very narrow and politically-ideologically driven view on increasingly controversial issues as to which there is a wide range of opinion among professionals. WPATH explicitly views itself as not merely a scientific organization, but also as an advocacy organization. *These are, obviously, conflicted, incompatible, and contradictory goals.* (Levine, *Reflections*, at 240.) WPATH is supportive to those who want Sex Reassignment Surgery ("SRS") even though such surgery is *not supported by credible, reliable-valid scientific research*, not accepted by the

relevant scientific community, and has no known error rates, and no careful systematic follow-up using agreed upon criteria to even assess multifaceted failure rates. Skepticism as to the benefits of SRS to patients, and strong alternate views, are not well tolerated in discussions within the organization. Such views have been literally shouted down and effectively silenced by the large numbers of nonprofessional adults who attend the organization's biennial meetings. Such "mob rule" is quite incompatible with appropriate, competent methodological discussions.

49. The Standards of Care ("SOC") is the product of an enormous effort, but it is not a politically neutral document. WPATH aspires to be both a scientific organization and an advocacy group for the transgendered. These aspirations are clearly in sharp conflict. The most serious limitations and defects of the Standards of Care, however, are not primarily political. They are caused by the decades-long and continuing lack of credible, rigorous research in the field, which allows room for passionate convictions and ongoing controversies on how to care for the transgendered. See, e.g. Vrouenraets et al, *Early Medical Treatment of Children and Adolescents With Gender Dysphoria: An Empirical Ethical Study*, *Journal of Adolescent Health* 57 (2015) 367e373. [The Endocrine Society and the World Professional Association for Transgender Health published guidelines for the treatment of adolescents with gender dysphoria (GD). The guidelines recommend the use of gonadotropin-releasing hormone agonists in adolescence to suppress puberty. However, in actual practice, *no consensus exists whether to use these early medical interventions ...* Conclusions: As long as *debate* remains on these seven themes and *only limited long-term data are available, there will be no consensus on treatment*. Therefore, more systematic interdisciplinary and (worldwide) multi-center research is required.]

50. In recent years, WPATH has fully adopted — in the absence of reliable-valid scientific research — some mix of the medical and civil rights paradigms. It has downgraded the role of

counseling or psychotherapy as a requirement for these life-changing processes. WPATH no longer considers preoperative psychotherapy to be a requirement. It is important to WPATH that the person has gender dysphoria; the pathway to the development of this state is not. (Levine, *Reflections*, at 240.) The trans person is assumed to have thoughtfully considered his or her options before seeking hormones, for instance. In clear violation of ethics rules, licensing regulations, and legal requirements — informed consent is neither standardized nor reasonably complete. The informed consent process is essential to protect the fundamental right of all patients to control their health care with informed choices. Informed consent documentation is needed to protect the doctor and the patient by verifying that the patient understands the potential benefits and the risk of specific harms including the risks of proceeding with such experimental gender affirmation treatments in the face of the ongoing lack of scientific evidence that might demonstrate these treatments are safe and effective. Additional risks include the lack of any credible long term scientific follow-up studies showing the safety and effectiveness of such experimental treatments over time. Finally, informed consent documents should verify a patient has been presented with and thoughtfully considered alternative treatments including no treatment. It should be noted that these informed consent processes are often violated by practitioners especially in treatment industries shaped by political ideology.

51. Most psychiatrists and psychologists who treat patients suffering sufficiently severe distress from gender dysphoria to seek inpatient psychiatric care are not members of WPATH. Many psychiatrists and psychologists who treat some patients suffering gender dysphoria on an outpatient basis are not members of WPATH. WPATH represents a self-selected subset of the profession along with its many non-professional members; it does not capture the clinical experiences of others. WPATH claims to speak for the medical profession; however, it does not

welcome skepticism nor competent scientific debate and analysis and therefore, deviates from the philosophical core of medical science.

52. For example, in 2010 the WPATH Board of Directors voted (note this is a consensus-seeking and not a reliable-valid scientific methodology) to issue a statement advocating that incongruence between sex and felt gender identity should cease to be identified in the DSM as a pathology. This position was debated but voted down (note this is a consensus-seeking and not a reliable-valid scientific methodology) adopted by the (much larger) American Psychiatric Association, which maintained the definitions and diagnoses of gender dysphoria as a pathology in the DSM-5 manual issued in 2013. By declaring that all forms of gender identity (some list over 120 different labels) are normal, the WPATH voting process involved fiat and not a proper-rigorous scientific analysis and consideration of alternate ways of defining mental abnormalities. The WPATH voting process was done to bolster the self-esteem of patients and to decrease social discrimination. It was not based on evidence. See, WPATH *De-Psychopathologisation Statement* (May 26, 2010), available at wpath.org/policies (last accessed January 21, 2020).

53. In my experience some members of WPATH have little ongoing experience with the mentally ill, and many trans care facilities are staffed by Mental Health Professionals (MHPs) who are not deeply experienced with recognizing and treating frequently associated psychiatric comorbidities. Because the 7th version of the WPATH Standards of Care recommendations deleted the requirement for psychotherapy, trans care facilities that consider these standards sufficient are permitting patients to be counseled to transition by means of social presentation (patient self-report), hormones, and surgery by individuals inexperienced with ongoing psychotherapy rather than those with medical or PhD degrees who are more likely during their careers to have considered the developmental forces shaping identity and behavior.. As a result of the downgrading of the role

of the psychiatric assessment of patients, new “gender affirming” clinics have arisen in many urban settings that quickly (sometimes within an hour’s time) recommend transition. Concerned parents who brought their child or teen to a professional office expecting to learn what is going on with their child instead often leave feeling overwhelmed, disoriented, and fearful for the future health and safety of that child. Some report being treated as though if they are the enemy of the child because they are not immediately supportive of the clinics’ affirmative responses. I am concerned that such defective practices are increasingly wide-spread. Such practices are the result of political advocacy and are not based on credible, reliable-valid science. Patients and their families are not told they are entered an experimental and potentially dangerous process.

III. SOCIAL TRANSITION OF PRE-PUBERTAL CHILDREN IS A MAJOR, EXPERIMENTAL, AND CONTROVERSIAL PSYCHOTHERAPEUTIC INTERVENTION THAT SUBSTANTIALLY CHANGES OUTCOMES.

54. A distinctive and critical characteristic of juvenile gender dysphoria is that multiple studies from separate groups and at different times have reported that in the large majority of patients, absent a substantial intervention such as social transition and/or hormone therapy, gender dysphoria does *not* persist through puberty. A recent article reviewed 11 existing follow-up studies and reported that “every follow-up study found the same thing: By puberty, the majority of GD children ceased to want to transition.” (Cantor at 1.) Another author reviewed the existing studies and reported that in “prepubertal boys with gender discordance See, S. Adelson & American Academy of Child & Adolescent Psychiatry (2012), Practice Parameter on Gay, Lesbian, or Bisexual Sexual Orientation, Gender Nonconformity, and Gender Discordance in Children and Adolescents, J. Am. Acad Child Adolescent Psychiatry 51(9) 957 at, 963 (“Practice Parameter”).

“the cross gender wishes usually fade over time and do not persist into adulthood, with only 2.2% to 11.9% continuing to experience gender discordance.” A third summarized the existing data as showing that “Symptoms of GID at prepubertal ages decrease or disappear in a considerable percentage of children (estimates range from 80-95%).” A 2021 publication found that 12% of previously evaluated grade school aged children persisted in their trans identities many years later. (Singh, Bradley, and Zucker, *Frontiers of Psychiatry*. See, P. T. Cohen-Kettenis, H. A. Delemarre-van de Waal et al. (2008), *The Treatment of Adolescent Transsexuals: Changing Insights*, *J. Sexual Medicine* 5(8) 1892 at 1895.

55. It is not yet known how to distinguish those children who will desist from that small minority whose trans identity will persist. (Zucker, *Gender Dysphoria in Children and Adolescents*, in *Principles and Practices of Sex Therapy* 6th edition, Guilford Press, 2020; Levine, *Ethical Concerns*, at 9.) Even severity of gender dysphoria is not a strong predictor of persistence. It is also apparent in the adolescent phenomenon of rapid onset of gender dysphoria following a gender normative childhood that childhood gender identity is not inherently stable. Some of these individuals desist and others evolve dramatically to become more non-binary and accepting of their complex male and female identifications.

56. Desistance (a patients’ willing reacceptance of their biological sex through normal developmental processes) within a relatively short period may also be a common outcome for post-pubertal youths who exhibit recently described “rapid onset gender disorder.” I observe an increasingly vocal online community of young women who have reclaimed a female identity after claiming a male gender identity at some point during their teen years. However, reliable-valid scientific data on outcomes for this age group with and without therapeutic interventions is not yet available. A recent review of de-transitioning claimed to have identified 60,000 case histories in

a search of proliferating websites devoted to this topic (Pablo Exposito-Campos. A typology of gender detransition and its implications for health care providers J Sex & Marital Therapy 2020 <https://doi.org/10.1080/0092623x.2020.1869126>). In the past WPATH has simply declined to discuss this vital topic, another example of WPATH's political consensus-seeking, *increasingly anti-science methodology*.

57. In contrast, there is now data that suggests that a therapy that encourages social transition dramatically changes outcomes and often “locks in” a patient’s journey into a life course of dependence on experimental hormone “treatments”. A prominent group of authors has written that “The gender identity affirmed during puberty appears to predict the gender identity that will persist into adulthood.” Similarly, a comparison of recent and older studies suggests that when an “affirming” methodology is used with young children, a substantial proportion of children who would otherwise have desisted by adolescence—that is, achieved comfort identifying with their natal sex—instead persist in a transgender identity. (Zucker, *Myth of Persistence*, at 7.)¹⁸

58. Indeed, a review of multiple studies of boys treated for gender dysphoria across the last three decades found that early social transition to living as the opposite sex severely reduces the likelihood that the child will revert to identifying with the child’s natal sex, Studies that began before the widespread use of social transition for young children reported desistance rates in the range of 80-98%. A more recent study reported that fewer than 20% of boys who engaged in a partial or complete transition prior to puberty desisted when surveyed at age 15. See (T.D. Steensma, J.K. McGuire et al. (2013), *Factors Associated with Desistance & Persistence of Childhood Gender Dysphoria: A Qualitative Follow-up Study*, J. of the Am. Academy of Child and Adolescent Psychiatry. 52, 582. ; See, C. Guss et al. (2015), Transgender and Gender

Nonconforming Adolescent Care: Psychosocial and Medical Considerations, Curr. Opin. Pediatrics 26(4) 421 at 421 (“TGN Adolescent Care”).

3) Another study found that social transition by the child was found to be strongly correlated with persistence for natal boys, but not for girls. (Zucker, *Myth of Persistence*, at 5 (citing T.D. Steensma, J.K. McGuire et al. (2013), *Factors Associated with Desistance & Persistence of Childhood Gender Dysphoria: A Qualitative Follow-up Study*, J. of the Am. Academy of Child and Adolescent Psychiatry. 52, 582.)

Some vocal practitioners of prompt affirmation and social transition claim that essentially *no* children who come to their clinics exhibiting gender dysphoria or cross-gender identification desist in that identification and return to a gender identity consistent with their biological sex.²⁰ This is a very large change as compared to the desistance rates documented apart from social transition. Some researchers who generally advocate prompt affirmation and social transition also acknowledge a causal connection between social transition and this change in outcomes. See, Guss, *TGN Adolescent Care*, at 2. “The gender identity affirmed during puberty appears to predict the gender identity that will persist into adulthood.” “Youth with persistent TNG [transgender, nonbinary, or gender-nonconforming] identity into adulthood . . . are more likely to have experienced social transition, such as using a different name . . . which is stereotypically associated with another gender at some point during childhood.”

59. Accordingly, I agree with a noted researcher in the field who has written that social transition in children must be considered “a form of psychosocial treatment.” (Zucker, *Debate*, at 1.)

60. So far as I am aware, no study yet reveals whether the life-course mental and physical health outcomes for this relatively new class of “persisters” are more similar to the non-transgender

population, or to the notably worse outcomes exhibited by the transgender population generally. See, e.g., B. Ehrensaft (2015), *Listening and Learning from Gender-Nonconforming Children*, *The Psychoanalytic Study of the Child* 68(1) 28 at 34: “In my own clinical practice . . . of those children who are carefully assessed as transgender and who are allowed to transition to their affirmed gender, we have no documentation of a child who has ‘desisted’ and asked to return to his or her assigned gender.”

61. However, I agree with Zucker who has written, “...we cannot rule out the possibility that early successful treatment of childhood GID [Gender Identity Disorder] will diminish the role of a continuation of GID into adulthood. If so, successful treatment would also reduce the need for the long and difficult process of sex reassignment which includes hormonal and surgical procedures with substantial medical risks and complications.” See, Zucker, *Myth of Persistence*, at 8 (citing H. Meyer-Bahlburg (2002), *Gender Identity Disorder in Young Boys: A Parent- & Peer-Based Treatment Protocol*, *Clinical Child Psychology & Psychiatry* 7, 360 at 362.).

By the same token, a therapeutic methodology for children that *increases* the likelihood that the child will continue to identify as the opposite gender into adulthood will *increase* the need for the long and potentially problematic processes of hormonal and genital and cosmetic surgical procedures.

62. Given these facts, *encouraging social transition in children remains controversial*. Supporters of such transition acknowledge that “Controversies among providers in the mental health and medical fields are abundant . . . These include differing assumptions regarding . . . the age at which children . . . should be encouraged or permitted to socially transition These are complex and providers in the field continue to be at odds in their efforts to work in the best interests of the youth they serve.” See, A. Tishelman et al. (2015), *Serving Transgender Youth: Challenges*,

Dilemmas and Clinical Examples, Prof. Psychol. Res. PR. at 11, DOI: 10.1037/a0037490 (“*Serving TG Youth*”) Transition then, should be undertaken only subject to standards, protocols, and reviews appropriate to actual clinical experiments [Clinical experiments involve time-honored careful processes with Institutional Review Board — human subjects protections — approval required, a predetermined method of evaluation, primary and secondary endpoints and safeguards to protect the rights of patients to truly informed consent. These protections are not present in the Transgender Treatment Industry when vulnerable patients are receiving “treatments” that lack sufficient proof of efficacy and safety.]

63. In sum, therapy for young children that encourages transition cannot be considered to be neutral, but instead *is an experimental procedure* that has a high likelihood of changing the life path of the child, with highly unpredictable effects on mental and physical health, suicidality, and life expectancy. Claims that a civil right is at stake do not change the fact that what is proposed is a social and medical experiment on vulnerable patients. (Levine, *Reflections*, at 241.)

IV. THE AVAILABLE DATA DOES NOT SUPPORT THE CONTENTION THAT “AFFIRMATION” OF TRANSGENDER IDENTITY REDUCES SUICIDE OR RESULTS IN BETTER PHYSICAL OR MENTAL HEALTH OUTCOMES GENERALLY.

64. I am aware that organizations including The Academy of Pediatrics and Parents, Families and Friends of Lesbians and Gays (PFLAG)) have published statements that suggest that all children who express a desire for a transgender identity should be promptly supported in that claimed identity. This position appears to rest on the belief—which is widely promulgated by certain advocacy organizations—that science has already established that prompt “affirmance” is best for all patients, including all children, who present indicia of transgender identity. As I discuss later below, this belief is scientifically incorrect, and ignores both what is known and what is unknown.

65. It is instructive to consider how policies are constructed by professional and lay organizations. Professional association vote on policies that are formulated in small committees. Such consensus processes are not a reliable valid scientific methodology. These professional, political, or community support groups do not rely upon scientifically tested methodologies, although they claim to have done so. All methodologically informed workers, even among those who work in this arena, have in the past and continue to conclude that there is low level science underlying treatment patterns and the policies that encourage them. A “low” level is defined by specific criteria of validity or trustworthiness.

Professional associations have a tainted history of supporting unproven, controversial notions that were later shown to be improper, unreliable, and/or unethical. For example, the American Medical Association supported eugenic proposals to “improve the quality of the human stock” by coercive sterilization of “defective and undesirable Americans” and selective breeding. During the 1890s the renowned surgeon Albert Ochsner was invited to speak about his vasectomy procedure to the meeting of the American Medical Association. He recommended vasectomies to prevent the reproduction of “criminals, chronic inebriates, imbeciles, perverts, and paupers.” (See, Ochsner, AJ, Surgical treatment of habitual criminals. JAMA, 1899:32:867-868). The AMA’s support was a political not a scientific process.

Similarly, the American Breeders Association founded a Eugenics Record Office with an advisory board that included a Harvard physiologist, a Princeton psychiatrist, a University of Chicago economist, and a Rockefeller Institute for Medical Research recipient of the Nobel Prize in Medicine. This movement was focused on “terminating the bloodlines” of the “submerged lower ten percent of the population with ‘defective germ-plasm’”. (See, Black, E. War Against the Weak, New York, NY, 2003).

With the support of the AMA, a Model Eugenics Sterilization Law was proposed to authorize sterilization of those supported in institutions or maintained at public expense. The model law encompassed the “feeble-minded, insane, criminalistic, epileptic, inebriate, diseased, blind, deaf, deformed, and dependent” — including “orphans, ne’er-do-wells, tramps, the homeless and paupers”. Eighteen states passed laws based on the 1922 model legislation and sixty-four thousand people were forcibly sterilized.

The lesson from the eugenics era is that associations can lend their weight and prestige to social movements believing that they are speaking from a foundation of science when in fact they are articulating political or ideological concepts. Such pseudoscientific voting consensus processes are neither valid, reliable, nor evidence-based.

This methodological critique is relevant to the understanding of WPATH. The American Academy of Pediatrics, the American Endocrine Society American Psychiatric Association, the American Psychological Association and similar groups have voted (not a scientific methodology) to declare supportive policies that are clearly not based on credible, reliable-valid science. These policies often do not acknowledge the glaring background deficiencies of what they put forward. Beyond the policy is the absence of controlled studies, the absence of prospective follow up studies and the discussion of the error rate of interventions. It might be useful to consider that there is a loose entity that can be labelled the Transgender Treatment Industry (TTI). The TTI generates considerable income for hospitals, clinicians, and pharmaceutical companies. Members of the TTI have a vested interest in believing that science has already justified their existence. As sterilization is the expected adult outcome of endocrine and surgical treatments of the procedures undertaken in youth, the TTI must have developed strong rationalizations to justify creating infertility. Will one day the medical profession look at support for transitioning youth in the same manner the

eugenics movement is now regarded? (See, Hruz, PW, Mayer, LS, and McHugh, PR, "Growing Pains: Problems with Puberty Suppression in Treating Gender Dysphoria," The New Atlantis, Number 52, Spring 2017 pp. 3 -36 ; See also, McHugh, P., Psychiatric Misadventures, The American Scholar, Vol. 62, No. 2 (Spring 1993), pp. 316-320 ;

The DSM and the International Classification of Diseases- ICD) system have confused courts in the past. These catalogues of recognized diseases are produced by consensus-seeking methodologies (non-scientific voting) which are presented as based on competent science, but actually lack robust reliability and validity data and provide no error rates. They are created by a committee voting system that submits recommendations to other committees. Disease categories are voted upon — voting is not a scientifically valid methodology (See, eugenics history). Both the DSM and the ICD are essentially medical dictionaries of disorders designed to standardize the use of diagnostic labels and are primarily useful to insurance companies. When the DSM-5 was published, the NIH made clear in public that research using its categories would not be supported because of the DSM-5's lack of validity. When it was recommended to put Gender Incongruence in a separate section of the ICD, authors wrote that it was designed to decrease social discrimination against and bolster self esteem of transgendered persons. See Reed GM, Drescher J, Krueger RB, Atalla E, Cochran SD, First MB, Cohen-Kettenis PT, Arango-de Montis I, Parish SJ, Cottler S, Briken P, Saxena S. Disorders related to sexuality and gender identity in the ICD-11: revising the ICD-10 classification based on current scientific evidence, best clinical practices, and human rights considerations. World Psychiatry. 2016 Oct;15(3):205-221. doi: 10.1002/wps.20354. Erratum in: World Psychiatry. 2017 Jun;16(2):220. PMID: 27717275; PMCID: PMC5032510.

**The Knowledge Base Concerning The Causes And Treatment
Of Gender Dysphoria Has Low Scientific Quality**

66. In 2009 the Endocrine Society published clinical guidelines for the treatment of patients with persistent gender dysphoria. See, Hembree, W. C. *et al.* Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab* 94, 3132-3154, doi:10.1210/jc.2009-0345 (2009)). The recommendations include temporary suppression of pubertal development of children with GnRH agonists (hormone blockers normally used for children experiencing precocious puberty) followed by hormonal treatments to induce the development of secondary sexual traits consistent with one's gender identity. This guideline used the GRADE (Recommendations, Assessment, Development, and Evaluation) system for rating clinical recommendations. The publication stated, "the strength of recommendations and the quality of evidence was low or very low." Low recommendations indicate "Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate". Very low recommendations mean that "any estimate of effect is very uncertain". These guidelines were updated eight years later. See, Hembree, W. C. *et al.* Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*, doi:10.1210/jc.2017-01658 (2017) ' The low quality of evidence..... persists to the current day as the controversy over these "treatments" is accelerating in recent years."

Similarly, a 2020 [Cochrane review](#) of hormonal treatment outcomes for male-to-female transitioners older than 16 years found "insufficient evidence to determine the efficacy or safety of hormonal treatment approaches for transgender women in transition." It is remarkable that decades after the first transitioned male-to-female patient, quality evidence for the benefit of transition is still lacking. See, Haupt, C., Henke, M. *et. al.*, [Cochrane Database of Systematic](#)

Reviews Review - Intervention, Antiandrogen or estradiol treatment or both during hormone therapy in transitioning transgender women, 28 November 2020. <https://doi.org/10.1002/14651858.CD013138.pub2> at <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013138.pub2/full>

Two systematic reviews commissioned by the US-based Endocrine Society in 2017 concur with the finding of the weak evidence base, stating that the finding of benefits of hormonal interventions in terms of "psychological functioning and overall quality of life" comes from "low-quality evidence (i.e., which translates into low confidence in the balance of risk and benefits)." Despite this sober assessment, the Endocrine Society instructed clinicians to proceed with treating gender-dysphoric youth with hormonal interventions in its guidelines, which have now been broadly adopted by a number of medical societies.

In The Society for Evidence-Based Gender Medicine (SEGM)'s view, the "low confidence in the balance of risks and benefits" of hormonal interventions calls for extreme caution when working with gender-dysphoric youth, who are in the midst of a developmentally-appropriate phase of identity exploration and consolidation. While there may be short-term psychological benefits associated with the administration of hormonal interventions to youth, they must be weighed against the long-term risks to bone health, fertility, and other as yet-unknown risks of life-long hormonal supplementation.

Further, the irreversible nature of the effects of cross-sex hormones, and the potential for puberty blockers to alter the natural course of identity formation should give pause to all ethical clinicians. Studies consistently show that the vast majority of patients with childhood-onset gender distress who are not treated with "gender-affirmative" social transition or medical interventions grow up to be LGB adults. However, socially-transitioned and puberty-suppressed children have

much higher rates of persistence of transgender identification (96%), necessitating future invasive and risky treatments. The trajectory of the novel, and currently the most common presentation of gender dysphoria, which emerges for the first time in adolescence following a gender-normative childhood is unknown. The increasing number of desisters and detransitioners suggest the rate of regret within this novel cohort will not be as rare as previously estimated.

It is SEGM's position that the significant uncertainties regarding the long-term risk/benefit profile of gender-affirmative hormonal interventions call for noninvasive approaches (e.g. psychotherapy, social support, coping and resilience training,) as the first line of treatment for youth. If pursued, invasive and potentially irreversible interventions for youth should only be administered in clinical trial settings with rigorous study designs capable of determining whether these interventions are beneficial. In addition to undergoing rigorous psychological and psychiatric evaluations, patients and their families should participate in a valid informed consent process. This process must accurately disclose the many uncertainties regarding the long-term mental and physical health outcomes of these experimental interventions. See, Spyridoula Maraka, Naykky Singh Ospina, Rene Rodriguez-Gutierrez, Caroline J Davidge-Pitts, Todd B Nippoldt, Larry J Prokop, M Hassan Murad, Sex Steroids and Cardiovascular Outcomes in Transgender Individuals: A Systematic Review and Meta-Analysis, *The Journal of Clinical Endocrinology & Metabolism*, Volume 102, Issue 11, 1 November 2017, Pages 3914–3923, <https://doi.org/10.1210/jc.2017-01643>

67. Recently several countries reviewed existent relevant scientific data

a. Finland suggested that clinicians wait until age 26 to administer hormones and surgical treatments for trans individuals.

b. Sweden found no scientific studies that explain the increase in incidence in children and adolescents who seek the health care because of gender dysphoria. They found no studies on changes in prevalence of gender dysphoria over calendar time, nor any studies on factors that can affect the societal acceptance of seeking for gender dysphoria. Studies on long-term effects of gender affirming treatment in children and adolescents are few, especially for the groups that have appeared during the recent decennium. The scientific activity during 2018 and 2019. seems high. Almost all identified studies are observational, some with controls and some with evaluation before and after gender affirming treatment. No relevant randomized controlled trials in children and adolescents were found.

A number of relevant issues were not considered during Sweden's review: proportion of care seekers who qualify for a formal diagnosis of gender dysphoria; proportion of children with gender dysphoria who have been given puberty blockers; proportion of teens administered cross-sex hormones; proportion who obtain surgery. See, Swedish Agency for Health Technology Assessment and Assessment of Social Services, "Gender dysphoria in children and adolescents: an inventory of the literature: A systematic scoping review at <https://www.sbu.se/307e>

c. Great Britain: the National Institute of Health and Care Excellence (NICE) reviewed the treatments offered for Gender Dysphoria in Great Britain in 2020. , NICE undertook two systematic evidence reviews of the use of GnRH agonists ("puberty blockers") and cross-sex hormones as treatments for gender dysphoric patients <18 years old. These reviews were led by Dr Hilary Cass OBE and published in March 2021. The evidence for using puberty blocking drugs to treat young people struggling with gender identity is "very low quality." The studies were small and "subject to bias and confounding". ... "The quality of evidence for these outcomes was assessed as very low certainty." ... When the clinical effectiveness of GnRH analogues was

compared with psychological support, social transitioning but no medication or no intervention NICE could not draw conclusions because of the (defective) way the studies had been designed. The studies were "all small" and lacked control groups. ... There was "very little data" on any additional interventions - such as counseling or whether other medications were provided along with taking puberty blockers. The review found no evidence of cost-effectiveness of treatment. See, National Institute for Health and Care Excellence - NICE, Evidence review: Gonadotrophin releasing hormone analogues for children and adolescents with gender dysphoria, 11 March 2021, at <https://www.evidence.nhs.uk/document?id=2334888&returnUrl=search%3fq%3dtransgender%26s%3dDate>

The NICE review of cross-sex hormones after age 16 looked at improved mental health, quality of life and body image. The evidence was of "very low" quality. "Any potential benefits of gender-affirming hormones must be weighed against the largely unknown long-term safety profile of these treatments in children and adolescents with gender dysphoria," See, National Institute for Health and Care Excellence - NICE, Evidence review: Gender-affirming hormones for children and adolescents with gender dysphoria, 11 March 2021, at <https://www.evidence.nhs.uk/document?id=2334889&returnUrl=search%3ffrom%3d2021-03-10%26q%3dEvidence%2bReview%26to%3d2021-04-01>

d. A Review by Professor Carl Heneghan and editor of British Medical Journal Findings echo what has just been stated but emphasized the exponential rise in referrals to Gender Identity Service since 2011. This has been noted by many others see Arch Dis Child 2018;103:631–6. [doi:10.1136/archdischild-2018-314992](https://doi.org/10.1136/archdischild-2018-314992). The BMJ review noted serious methodological flaws in research and reviews, saying, "together these reviews included 16 studies with 1,132 participants

(transgender males (54%); transgender females (37%) and (7.6%) control subjects reported. *Controls were not matched for important confounders, which means caution should be applied to any conclusions drawn” and “We found no randomized controlled trials or controlled trials.”...* Multiple studies were funded by the drug manufacturers “Six studies were funded by industry: 4 received funding from Ferring Pharmaceuticals ([Delemarre-van de Waal 2006](#), [Staphorsius \(2015\)](#), [Schagen 2016](#) and [Hannema 2017](#)).... “The numbers in the ten studies are small and most are retrospective case reports or small case series. Many are done in single clinics and lack long-term longitudinal outcomes on the effects (both benefits and harms) of puberty blockers. It is also hard to disentangle effects from the use of gender affirming hormones. We found four studies reporting on the use of GnHRa alone: [Schagen 2016](#); [Staphorsius 2015](#); [Costa 2015](#) and [Delemarre-van de Waal 2006](#).

“Problems within these studies, however, make it difficult to assess whether early pubertal changes regress under GnRHa treatment and whether prolonged puberty suppression is safe. For example, there is a lack of controls, and in one study that included controls, these were inadequate as relatives and friends of the participants were asked to participate, serving as age-matched controls. A lack of blinding was also problematic. One study ([Costa 2015](#)) that focused on a measure of psychosocial well-being highlighted that getting older has previously been positively associated with maturity and well-being (see [Getting older, getting better? Personal strivings and psychological maturity across the life span.](#))

The BMJ review also discussed Gender-affirming cross-sex hormone hormones (CSHs). They noted, “Oestrogens and testosterone induce masculine or feminine physical characteristics, and should only be taken in the context of medical supervision to monitor risks (e.g., [polycythaemia](#) in transgender males, [venous thromboembolism](#) in transgender females).

For transgender females, oestrogen therapy alone is often insufficient to produce the desired feminizing effects. Other treatments are therefore used in an off label manner. For example spironolactone, an aldosterone antagonist with weak oestrogenic properties is commonly used to support oestrogen therapy – off label. Cyproterone acetate has progestational and antiandrogenic properties, but it can lead to hepatic toxicity including jaundice, hepatitis. Hepatic failure has also been reported (fatalities reported, usually after several months, at dosages of 100 mg and above). See, Gender-affirming hormone in children and adolescents, British Medical Journal, 25th February 2019 at <https://blogs.bmj.com/bmjebmspotlight/2019/02/25/gender-affirming-hormone-in-children-and-adolescents-evidence-review/>

68. In evaluating claims of scientific or medical knowledge, it is important to understand that it is axiomatic in science that no knowledge is absolute, and to recognize the widely accepted hierarchy of reliability when it comes to “knowledge” about medical or psychiatric phenomena and treatments. Unfortunately, in this field opinion and ideological fervor are too often *confused with reliable knowledge*, rather than clearly locating what exactly is scientifically known. In order of increasing confidence, such “knowledge” may be based upon data comprising of:

a. Expert opinion—it is perhaps surprising to educated laypersons that expert opinion standing alone is the lowest form of knowledge, the least likely to be proven correct in the future, and therefore does not garner as much respect from professionals as what follows.

b. A single case or series of cases (what could be called anecdotal evidence);
(Levine, *Reflections*, at 239.)

c. A series of cases with a control group;

d. A cohort study;

e. A randomized double-blind clinical trial;

f. A review of multiple trials;

g. A meta-analysis of multiple trials that maximizes the number of patients treated despite their methodological differences to detect trends from larger data sets. The current status of the field of gender affirmation treatments has been labelled “low quality” science by multiple reviews with existing studies suffering from *numerous methodological defects and misreporting of data* thus the field is *still at the experimental stage* lacking in general acceptance and without known error rates.

68. Before the recent reviews discussed above were published, prominent voices in the field have emphasized the severe lack of scientific knowledge in this field. The American Academy of Child and Adolescent Psychiatry has recognized that “Different clinical approaches have been advocated for childhood gender discordance. . . . There have been no randomized controlled trials of any treatment. . . . [T]he proposed benefits of treatment to eliminate gender discordance...must be carefully weighed against... possible deleterious effects.” (Adelson et al., *Practice Parameter*, at 968–69.) Similarly, the American Psychological Association has stated, “...because no approach to working with [transgender and gender nonconforming] children has been adequately, empirically validated, consensus does not exist regarding best practice with pre-pubertal children.” See, American Psychological Association, *Guidelines for Psychological Practice with Transgender & Gender Nonconforming People* (2015), *Am. Psychologist* 70(9) 832 at 842.

69. Critically, “there are *no randomized control trials* with regard to treatment of children with gender dysphoria.” (Zucker, *Myth of Persistence*, at 8.) On numerous critical questions relating to cause, developmental path if untreated, and the effect of alternative treatments, the knowledge base remains primarily at the level of the practitioner’s exposure to individual cases,

or multiple individual cases. As a result, claims to certainty are not justifiable. (Levine, *Reflections*, at 239.) See, American Psychological Association, Guidelines for Psychological Practice with Transgender & Gender Nonconforming People (2015), Am. Psychologist 70(9) 832 at 842.

70. Large gaps exist in the medical community's knowledge regarding the long-term effects of Sex Reassignment Surgery and other gender identity disorder treatments in relation to their positive or negative correlation to suicidal ideation, attempts, and completion. What is known, however, is not encouraging.

Effective Criticism of Recently Published Research

71. In 2020, Bränström and Panchankis, published a study claiming that “the longitudinal association between gender-affirming surgery and reduced likelihood of mental health treatment lends support to the decision to provide gender-affirming surgeries to transgender individuals who seek them.” They claimed their research provided the first empirical evidence that gender transition surgeries had long-term benefits. (See, Bränström R, Pachankis JE: Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: a total population study. Am J Psychiatry 2020; 177: 727–734.). Nine letters were submitted to the editor from MDs, PhDs, and other methodologists that clarified methodological blunders and/or what appear to be potentially manipulative deceptions. These were published in August 2020. The writers concluded that, “These methodological shortcomings preclude any statement on the suitability of early surgery in persons seeking treatment for gender non-congruence based on the results presented in this article.” They noted evidence supporting the theory that these “errors” could well be purposeful and designed to support an ideological perspective when they noted, “people diagnosed with gender incongruence have a dramatically worse overall mental health outcome (after “transitioning” treatments) than the general

population, which is, in fact, the answer to their stated aim and research question, but this (essential) finding is not even referred to in the title or in the Conclusions section of the article.” (See, Kalin, N.H., Reassessing Mental Health Treatment Utilization Reduction in Transgender Individuals After Gender-Affirming Surgeries: A Comment by the Editor on the Process by the Editor-in-Chief The American Journal of Psychiatry, Am J Psychiatry 2020; 177:764; doi: 10.1176/appi.ajp.2020.20060803; See also, Anckarsäter, H., (MD, Ph.D.) and Gillberg, C., (M.D., Ph.D.) Methodological Shortcomings Undercut Statement in Support of Gender-Affirming Surgery, Am J Psychiatry 2020; 177:764–765; doi: 10.1176/appi.ajp.2020.19111117 .

Other serious flaws were highlighted “For those whose last surgery was 10 or more years earlier, how many completed suicide, died of other causes, or left Sweden prior to study initiation?” The authors failed to find out. “A drop in hospitalizations for suicide attempts alone provides a very incomplete picture. When the data for such findings are accessible in the Swedish national registers, this omission is glaring. The lack of control subjects, the limited 1-year time frame, and the avoidance of examining completed suicides and psychiatric hospitalizations are substantial study shortfalls.” ... “The study supports only weak conclusions about psychiatric medication usage and nothing decisive about suicidality. In overlooking so much available data, this study lacks the evidence to support its pro gender-affirmation surgery conclusion.” See, Van Mol, A., , Laidlaw, M. K., Grossman, M., McHugh, P. , Gender-Affirmation Surgery Conclusion Lacks Evidence, Am J Psychiatry 177:8, August 2020 ajp.psychiatryonline.org 765.

“The study confirms the strong association between psychiatric morbidity and the experience of incongruity between gender identity and biological sex. However, the study does not demonstrate that either hormonal treatment or surgery has ANY effect on this morbidity. It seems that the main message of this article is that the incidence of mental health problems and suicide

attempts is especially HIGH in the year AFTER the completion of gender-affirming surgery [It is telling that the authors somehow ignored this most essential finding] ...” See, Curtis, D. (M.D., Ph.D.), Study of Transgender Patients: Conclusions Are Not Supported by Findings, Am J Psychiatry 2020; 177:766; doi: 10.1176/appi.ajp.2020.19111131.

“ The data presented in Figure 1 in the article support findings from previous studies showing that transgender individuals have baseline mental health distress that is higher than that of the general population, but it is not possible to conclude from these data whether gender-affirming surgery relieves that distress.”... “Because of the limitations in the study design, it is not possible to determine the cause of the differences in mental health service utilization or whether true reductions in psychological distress actually occurred. “Therefore, the authors’ conclusion that the results of their study should be interpreted to support policies that provide gender-affirming surgeries cannot be supported.” See, Malone, W. and Roman, S. , Calling Into Question Whether Gender-Affirming Surgery Relieves Psychological Distress, Am J Psychiatry 2020; 177:766–767; doi: 10.1176/appi.ajp.2020.19111149.

“ Bränström and Pachankis study on mental health treatment and suicide attempts ... is misleading because the study design is flawed.” “The authors first found what was already known ... the rate of psychiatric morbidity is much higher in persons with gender dysphoria compared with the general population (both before AND after “transitioning”). The authors then explored if the risk for mental health treatment changes as a function of years since starting HORMONAL treatment. They find NO effect (odds ratio = 1.0), but they do find a trend toward INCREASED risk of suicide attempts as a function of years since starting HORMONAL treatment. They somehow failed to publish this essential finding. In their key analysis, allegedly showing that gender-affirming surgery decreases risk for psychiatric treatment and suicide attempts, they relate

these negative outcomes to the number of years since surgery. Contrary to what the authors repeatedly claim, they do not employ a longitudinal design but conduct a retrospective analysis unfit for their research question. First, the authors include only persons who were alive in 2014. That means that those who died by SUICIDE before 2014—and hence were at highest risk for suicide attempt—are EXCLUDED ((Negligence or Fraud?) and confound the results. Second, any analysis starting with a negative event is bound to find a decreased risk for related negative outcomes with increasing time after the event. To exemplify this point, the rate of antidepressant treatment would decrease with time after a suicide attempt. This does not mean that suicide attempts cause a decrease in risk of antidepressant treatment; it is merely a case of regression toward the mean. Third, persons undergoing gender transition have, contact with mental health services in Sweden. After the transition, persons are followed up by endocrinologists and sometimes general practitioners; only those with persistent mental health issues are followed in psychiatric care. The authors' finding of lower rates of mental health treatment with increasing time after surgery is therefore not only a case of regression toward the mean, but it also follows from the standards of care and is not a proxy for improved mental health. Because the authors do not present data prior to gender affirming surgery, the study is uninformative with regard to the effects on psychiatric morbidity. Moreover, the authors miss the one conclusion that can be drawn: that the perioperative transition period seems to be associated with HIGH risk for SUICIDE attempt. Future research should use properly designed observational studies to answer the important question as to whether gender-affirming treatment affects psychiatric outcomes.” See, Landén, M. (M.D., Ph.D.) The Effect of Gender-Affirming Treatment on Psychiatric Morbidity Is Still Undecided, Am J Psychiatry 2020; 177:767–768; doi: 10.1176/appi.ajp.2020.19111165.

“The results confirm what is already known, that is, that as a group, persons with gender dysphoria suffer from poorer psychiatric health than the general population. However, the title of the article implies that gender corrective surgery promotes mental health in this group, and the authors conclude in the Abstract section that the study “lends support to the decision to provide gender affirming surgeries to transgender individuals who seek them.” In my opinion, this conclusion is not supported by the data presented in the article. The most straightforward method to test whether surgery contributes to better psychological health would be to compare the health of those who underwent surgery with those who did not. Of the persons diagnosed with gender dysphoria presented in the article, 1,018 had undergone surgery, while 1,661 had not. There were 22 individuals who were hospitalized in 2015 for a suicide attempt. The authors do not state how many of these individuals had received surgery, but this may be calculated by combining the data from Table 3 and Figure 1 in the article. Figure 1 shows the proportion of persons with gender dysphoria who were hospitalized for suicide attempt in 2015, grouped according to the time that had elapsed since the last gender-corrective surgery. Table 3 shows the number of individuals with gender dysphoria, grouped according to the time elapsed since last surgical operation (“Time since last gender-affirming surgical treatment”). By combining these data, we can calculate that 10 of the suicide attempts (2.8% of 353) occurred during the same year that the last surgical correction was made (“perioperative” group in Figure 1). Two cases occurred 1 year after the last surgical correction (0.9% of 221) and one case 2–3 years after the last surgical treatment (0.5% of 198), while none occurred more than 3 years after the last surgery. Thus, 13 individuals (10 plus two plus one) of the 22 persons who were hospitalized for a suicide attempt in 2015 had undergone gender corrective surgery. Consequently, nine of them (22 minus 13) had not undergone any gender-affirmation surgery. This corresponds to an odds ratio of 2.37 (95% CI= 1.01–

5.56, $p=0.047$). Hence, among the individuals examined in the study, the risk of being hospitalized for a suicide attempt was 2.4 times higher if they had undergone gender-corrective surgery than if they had not. Whether these factors involve a causal relationship (i.e., that surgery actually worsens the poor mental health in individuals with gender dysphoria) cannot be determined from such a study. Nevertheless, the data presented in the article do not support the conclusion that surgery is beneficial to mental health in individuals with gender dysphoria.” See, Wold, A. (M.D., Ph.D.) Gender-Corrective Surgery Promoting Mental Health in Persons With Gender Dysphoria Not Supported by Data Presented in Article, *Am J Psychiatry* 2020; 177:768; doi: 10.1176/appi.ajp.2020.19111170.

“Therefore, accounting for the increase in mental health issues from 2005, together with an assumption of **increased** mental health treatment due to this surgery, fits the data in the article and **overturns** the authors’ stated conclusions, suggesting that sex reassignment surgery is in fact associated with increased mental health treatment See, Ring, A. (PhD) and Malone, W. , Confounding Effects on Mental Health Observations After Sex Reassignment Surgery, *Am J Psychiatry* 2020; 177:768–769; doi: 10.1176/appi.ajp.2020.19111169.

Taken together, these nine separate criticisms and the editor’s decision to publish each of them in less than a year after e-publication, constitutes a illustration of the dangers of confirmation bias.

The authors admitted their conclusions were in error and that “more research” is needed to answer the questions they raised. The authors admitted, “Studies employing prospective cohort designs are needed to better understand suicidality within this group and its associations with gender-affirming care... (and)... When comparing the mental health treatment outcomes between the two groups (Table 1), we found no significant difference in the prevalence of treatment for

mood disorders and no significant difference in the prevalence of hospitalization-suicide attempts. “ Bränström and Panchankis admitted they had failed to note that “individuals diagnosed with gender incongruence who had received gender-affirming surgery were more likely to be treated for anxiety disorders compared with individuals diagnosed with gender incongruence who had NOT received gender-affirming surgery. ’and “While the design clearly establishes that individuals diagnosed with gender incongruence utilized more mental health care than the general population in 2015, especially during the perioperative period, like most extant research on the topic, *the design is incapable of establishing a causal effect* of gender affirming care on mental health treatment utilization. see Bränström, R. and Pachankis, J. , Toward Rigorous Methodologies for Strengthening Causal Inference in the Association Between Gender-Affirming Care and Transgender Individuals ’Mental Health: Response to Letters, Am J Psychiatry 2020; 177:769–772; doi: 10.1176/appi.ajp.2020.20050599.

In sum, too many ideologically tainted and methodologically defective research studies suffer from these kinds of serious errors, improper analyses and deceptive conclusions. Such poorly designed and improperly conducted research studies continue to prevent gender transition “affirmation” treatments from being generally accepted by the relevant scientific community. Finally, the Error Rates for such unproven, experimental “treatments” as well as for the foundational politically-based transgender ideology, are unknown, not peer-reviewed, and are thus unpublished.

72. Review of the Carmichael, et al, UK study of 2020: This research looked at short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. In sum, the authors ... “ *identified no changes in psychological function but noted that* ”changes in bone density were consistent with suppression

of growth”. Most importantly, the authors noted the lack of research support for such treatments, stating “Larger and longer-term prospective studies using a range of designs are needed to more fully quantify the benefits and harms of pubertal suppression in GD 44 patients had data at 12 months follow-up, 24 at 24 months and 14 at 36 months. All had normal karyotype and endocrinology consistent with birth-registered sex. All achieved suppression of gonadotropins by 6 months. The studies conclusions noted “We identified no changes in psychological function. Changes in BMD were consistent with suppression of growth. Larger and longer-term prospective studies using a range of designs are needed to more fully quantify the benefits and harms of pubertal suppression in GD” .” See, Polly Carmichael, Gary Butler, Una Masic, Tim J Cole, Bianca L DeStavola, Sarah Davidson, Elin M. Skageberg, Sophie Khadr, Russell Viner. Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. medRxiv 2020.12.01.20241653; doi:<https://doi.org/10.1101/2020.12.01.20241653> and <https://www.medrxiv.org/content/10.1101/2020.12.01.20241653v1> <https://www.medrxiv.org/content/10.1101/2020.12.01.20241653v1> BBC summary: <https://www.bbc.com/news/uk-55282113> “ Later reviewers noted a number of defects in the study design including the failure to follow up lost subjects over the nine-year study. There were only 44 patients available for analysis.; the study also lacked a control group; the study emphasized hypothesized biological origin of GD but excluded other possibilities; the study established that puberty blockers are highly likely to lead to cross-sex hormones and thus are not “easily reversible”; the authors also failed to note these drugs suppressed growth of height; the authors also failed to emphasize that self harm did not improve since they found no differences between baseline and later outcomes for overall psychological distress See also, Schumm, WR

and Crawford, DW, Is Research on Transgender Children What It Seems? Comments on Recent Research on Transgender Children with High Levels of Parental Support, The Linacre Quarterly, 2020, Vol. 87(1) 9-24. DOI: 10.1177/0024363919884799

73. Olson-Kennedy, J, has at times been an advocate for social transitioning of grade school youth and the employment of puberty blockers. Along with other researchers she summarized a number of the ongoing serious defects in the field's understanding of transgender patients. "Clinically useful information for predicting individual psychosexual development pathways is lacking." "Transgender youth are at high risk for poor medical and psychosocial outcomes [with or without affirmation treatments]." "Longitudinal data examining the impact of early social transition and medical interventions *are sparse*." "Existing tools to understand gender identity and quantify gender dysphoria *need to be reconfigured* to study a more diverse cohort of transgender individuals." Given their observations and their knowledge of the studies of non intervention leading to desistance, one must wonder how such advocates rationalize putting children on a path that will eventually lead to cross gender hormones and surgery. They have stated that "Extensive research is needed to improve understanding of gender dysphoria, and transgender experience, particularly among youth. Recommendations include *identification of predictors of persistence* of gender dysphoria from childhood into adolescence {cannot yet be done with scientific certainty}, and *a thorough investigation into the impact of interventions for transgender youth*. I agree with this recommendation but in my opinion we should first do careful, competent prospective controlled follow up studies and only *then* make potential hazardous policy recommendations that put patients at risk. Finally, they suggest that *examining the social environments of transgender youth is critical for the development of appropriate interventions* necessary to improve the lives of transgender people. Despite this recommendation, it is ironic that

such multi-disciplinary research, analysis, and treatment is now being blocked and threatened as “conversion therapy” by political advocates. [See, Olson-Kennedy, J, Cohen-Kettenis, P., et al., Research priorities for gender nonconforming/transgender youth gender identity development and biopsychosocial outcomes, *Current Opinion in Endocrinology & Diabetes and Obesity*: [April 2016 - Volume 23 - Issue 2 - p 172-179](#), doi: 10.1097/MED.0000000000000236]

Suicide, suicidal ideation, suicide attempts, suicidal manipulations

74. With respect to suicide risks, individuals with gender dysphoria are well known to have a higher risk of committing suicide or otherwise suffering increased mortality before and after not only social transition, but also before and after SRS. (Levine, *Reflections*, at 242.) For example, in the United States, the death rates of trans veterans are *comparable to those with schizophrenia and bipolar diagnoses but 20 years earlier* than expected. These crude death rates include significantly elevated suicide rates. (Levine, *Ethical Concerns*, at 10.) Similarly, researchers in Sweden and Denmark have reported on almost all individuals who underwent sex-reassignment surgery over a 30-year period. The Swedish follow-up study found a suicide rate in the post-Sex Reassignment Surgery (SRS) population *19.1 times greater than that of the controls after affirmation treatment*; both studies demonstrated elevated mortality rates from *medical and psychiatric conditions*. (Levine, *Ethical Concerns*, at 10.) See, C. Dhejne et al. (2011), Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden, *PLOS ONE* 6(2) e16885 (“Long Term”); R. K. Simonsen et al. (2016), Long-Term Follow-Up of Individuals Undergoing Sex Reassignment Surgery: Psychiatric Morbidity & Mortality, *Nordic J. of Psychiatry* 70(4).

75. Advocates of immediate and unquestioning affirmation of social transition in children who indicate a desire for a transgender identity sometimes assert that any other course will result

in a high risk of suicide in the affected children and young people. *Contrary to these assertions, no reliable-valid scientific studies show that affirmation of children (or anyone else) reduces suicide, prevents suicidal ideation, or improves long-term outcomes, as compared to either a “watchful waiting” or a psychotherapeutic model of response, as I have described above.*

A 2020 article, J. Turban et al., *Puberty Suppression for Transgender Youth and Risk of Suicidal Ideation*, Pediatrics 145(2), DOI: 10.1542/peds.2019-1725, has been incorrectly and misleadingly described in some press reports as demonstrating that administration of puberty suppressing hormones to transgender adolescents reduces suicide or suicidal ideation. The paper itself does not directly make that claim, nor permit that conclusion. It has been rigorously criticized for not emphasizing that both those treated and not treated with puberty blockers had high suicidal ideation rates and more children on these drugs were hospitalized for suicidal plans than the untreated. See, e.g., Hruz, Mayer and Schumm January 26m 2020, and M.Biggs [Puberty Blockers and Suicidality in Adolescents Suffering from Gender Dysphoria](#). Arch Sex Behav. 2020 Oct;49(7):2227-2229. doi: 10.1007/s10508-020-01743-6. Epub 2020 Jun 3.

76. Any discussion of suicide when considering younger children involves very long-range and *very uncertain, inaccurate* predictions. Suicide in pre-pubescent children is rare and the existing studies of gender identity issues in pre-pubescent children do *not* report significant incidents of suicide. *The current estimated suicide rate of trans adolescents is the same as teenagers who are in treatment for serious mental illness.* What trans teenagers do demonstrate is more suicidal ideation and attempts (however serious) than other teenagers. See, A. Perez-Brumer, J. K. Day et al. (2017), Prevalence & Correlates of Suicidal Ideation Among Transgender Youth in Cal.: Findings from a Representative, Population-Based Sample of High Sch. Students, J. Am. Acad Child Adolescent Psychiatry 56(9), 739 at 739.

77. In sum, ***claims that affirmation will reduce the risk of suicide for children are not based on credible, reliable-valid science***. Such claims overlook the lack of even short-term supporting data as well as the lack of studies of long-term outcomes resulting from the affirmation or lack of affirmation of transgender identity in children. It also overlooks the other tools that the profession does have for addressing depression and suicidal thoughts in a patient once that risk is identified including cognitive behavioral therapy and other proven interventions. (To Do Full citation?) (Levine, *Reflections*, at 242.)

A number of data sets have also indicated significant concerns about wider indicators of physical and mental health, including ongoing functional limitations including: abuse, depression, and psychiatric hospitalizations and increased cardiovascular disease, cancer, asthma, and COPD. Worldwide estimates of HIV infection among transgendered individuals are up to 17-fold higher than the cisgender population. Looking at such data may provide an indirect explanation for the high prevalence of suicidality both before and after transition from adolescence to older age among trans populations. See, (Levine, *Informed Consent*, at 6 ; See, also G. Zeluf, C. Dhejne et al. (2016), *Health, Disability and Quality of Life Among Trans People in Sweden—A Web-Based Survey*, BMC PUBLIC HEALTH 16(903), DOI: 10.1186/s12889-016-3560-5. See, C. Dhejne, R. Van Vlerken et al. (2016), *Mental Health & Gender Dysphoria: A Review of the Literature*, Int'l Rev. of Psychiatry 28(1) 44.

78. Similarly, ***no scientific studies show that affirmation of pre-pubescent children leads to more positive outcomes*** (mental, physical, social, or romantic) by, e.g., age 25 or older ***than does “watchful waiting” or ordinary psychotherapy***. Because children’s affirmation, social transition, and the use of puberty blockers for transgender children are a recent phenomenon, it could hardly be otherwise.

79. Thus, given the lack of credible science evidence for suicide reduction, transition of any sort must be justified, if at all, as a life-*enhancing* measure, not a lifesaving measure — although there is no credible to support either hypothesis. (Levine, *Reflections*, at 242.) In my opinion, this is an important fact that patients, parents, and even many MHPs fail to understand. They also often do not understand that the current gender affirmation “treatment” data for life saving or enhancement are so weak, sparse, and poorly gathered that they do not permit us to know if gender affirmation interventions will increase or decrease a patient’s risk of suicide or reduced depression *or even an improved life*. How many years will go by before such research is competently completed? See, C. Dragon, P. Guerino, et al. (2017), *Transgender Medicare Beneficiaries & Chronic Conditions: Exploring Fee-for-Service Claims Data*, LGBT Health 4(6) 404, DOI: 10.1089/lgbt.2016.0208.

V. KNOWN, LIKELY, OR POSSIBLE DOWNSIDE RISKS ATTENDANT ON MOVING QUICKLY TO “AFFIRM” TRANSGENDER IDENTITY IN CHILDREN.

80. As some research has already demonstrated, enabling and affirming social transition in a prepubescent child appears to be highly likely to increase the odds that the child will in time pursue pubertal suppression and persist in a transgender identity into adulthood. I consider the ethical implications of this intervention in the next section. Here, I emphasize that the Mental Health Professional (MHP), pediatrician, and parent must consider long-term as well as short-term implications of life as a transgender individual when deciding whether to permit or encourage a child to socially transition.

81. The multiple studies from different nations that have documented *the increased vulnerability of the adult transgender population to substance abuse, mood and anxiety disorders, suicidal ideation, and other health problems stand as a warning*: Given these well-documented data, *assisting a child down the road to becoming a transgender adult is an ominous*

decision. Data about trans adults remind all concerned that a casual assumption that transition will improve the child's life is ***not*** justified beyond his or her short term happiness about gender expression. The possibility that steps along this pathway, while lessening the relatively minor pain of gender dysphoria, *could lead to additional future sources of crippling emotional and psychological pain*, are too often not properly considered by advocates of social transition and not considered at all by the trans child. (Levine, *Reflections*, at 243.). The informed consent process for parents considering this option ethically should spell out short-term gains and long-term risks (beginning at early puberty risks). What follows is a discussion of the medical, social, and psychological risks of affirmation interventions ("transition").

A. Physical risks associated with transition

82. Sterilization. Sex Reassignment Surgery (SRS) that removes testes, ovaries, or the uterus is ***inevitably sterilizing and irreversible***. While by no means all transgender adults elect SRS, many patients do ultimately feel compelled to take this serious step in their effort to "live fully as the opposite sex". More immediately, practitioners recognize that the administration of cross-sex hormones, which is often viewed as a less radical measure, and is now increasingly done to minors, creates a risk of irreversible sterility. These risks have never been properly studied nor quantified in a systematic manner. As a result, even when treating a child, the MHP, patient, and parents must consider ***permanent loss of reproductive capacity (sterilization)*** to be one of the *major risks of starting down the road*. The risk that supporting social transition may put the child on a pathway that leads to intentional or unintentional permanent sterilization is particularly concerning given ***the disproportionate representation of minority and other vulnerable groups*** among children reporting a transgender or gender-nonconforming identity. See C. Guss et al., *TGN Adolescent Care* at 4 ("a side effect [of cross-sex hormones] may be infertility") and 5

(“cross-sex hormones . . . may have irreversible effects”); Tishelman et al., *Serving TG Youth* at 8 (Cross-sex hormones are “irreversible interventions” with “significant ramifications for fertility”). (*See supra* ¶ 21.)

83. Loss of sexual response. Puberty-blockers prevent maturation of the sexual organs and response. Some and perhaps many transgender individuals who transitioned as children and thus did not go through puberty consistent with their sex face significantly diminished sexual response as they enter adulthood, and ***are unable ever to experience orgasm***. To my knowledge, data quantifying this impact has not been published. In the case of males, the cross-sex administration of estrogen limits penile genital function. Much has been written about the negative psychological and relational consequences of anorgasmia among non-transgender individuals that is ultimately applicable to the transgendered. (Levine, *Informed Consent*, at 6.) (Perelman and Watters, 2016) Delayed Ejaculation in Handbook of Clinical Sexuality for. Mental Health Professionals 3rd edition, New York, Routledge).

84. Other effects of hormone administration. While it is commonly said that the effects of puberty blockers are reversible after cessation, in fact ***controlled, reliable-valid research studies have never been done*** as to how completely this is true. However, it is well known that ***many effects of cross-sex hormones cannot be reversed*** should the patient later regret his transition. This is dramatically evident among females 'deeper voice quality after testosterone administration and the loss of muscle mass among males on estrogen for long periods of time. After puberty, the individual who wishes to live as the opposite sex will in most cases *have to take cross-sex hormones for life*.

85. The long-term health risks of this major alteration of hormonal levels ***have not yet been quantified*** in terms of exact risk *thus appropriate, ethical, complete informed consent is not*

yet possible for such experimental “treatments”. However, a recent study found *greatly elevated levels of strokes and other acute cardiovascular events among male-to-female transgender individuals* taking estrogen. Those authors concluded, “it is critical to keep in mind that the risk for these cardiovascular events in this population must be weighed against the benefits of hormone.

32 See Tishelman et al., *Serving TG Youth* at 6-7 (Long-term effect of cross-sex hormones “is an area where we currently have *little research to guide us*”). treatment.” See, D. Getahun et al. (2018), *Cross-Sex Hormones and Acute Cardiovascular Events in Transgender Persons: A Cohort Study*, *Annals of Internal Medicine* at 8, DOI:10.7326/M17-2785.

Others similarly noted that administration of cross-sex hormones creates “an additional *risk of thromboembolic events*”—which is to say *blood clots* (Guss et al., *TGN Adolescent Care* at 5), *which are associated with strokes, heart attack, and lung and liver failure*. The young patient may feel, “I don’t care if I die young, just as long I get to live as a woman.” The mature adult may take a different view of such risks including the risk of reduced life expectancy. See, Blosnich, J. R., Brown, G. R., Wojcio, S., Jones, K. T., & Bossarte, R. M. (2014). Mortality among veterans with transgender-related diagnoses in the Veterans Health Administration, FY2000–2009. *LGBT Health*, 1, 269–276. doi:[10.1089/lgbt.2014.0050](https://doi.org/10.1089/lgbt.2014.0050)

86. Health risks inherent in complex surgery. Complications of surgery exist for each procedure, and complications in surgery affecting the reproductive organs and urinary tract can have significant anatomical and functional complications for the patient's quality of life.

87. Disease and mortality generally. The MHP, the patient, and in the case of a child the parent, must also be aware of the wide sweep of strongly negative health outcomes among transgender individuals. *Shortened life expectancy has been repeatedly documented* in Sweden, US, and Denmark. See, Levine, *Informed Consent*, at 5 (citing T. van de Grift, G. Pigot et al.

(2017), A Longitudinal Study of Motivations Before & Psychosexual Outcomes After Genital Gender-Confirming Surgery in Transmen, J. Sexual Medicine 14(12) 1621.).

B. Social risks associated with transition

88. Family and friendship relationships. Gender transition routinely leads to isolation from at least a significant portion of one's family in adulthood. In the case of a juvenile transition, this will be less dramatic while the child is young, but commonly increases over time as siblings who marry and have children of their own often do not wish the transgender individual to be in contact with those children. By adulthood, the friendships of transgender individuals tend to be confined to other transgender individuals (often "virtual" friends known only online) and the generally limited set of others who are comfortable interacting with transgender individuals. (Levine, *Ethical Concerns*, at 5.)

89. ***Long term psychological and social impact of medically induced sterility.*** The life-long negative emotional impact of infertility on both men and women has been well studied. While this impact has not been studied specifically within the transgender population, the opportunity to be a parent is likely a human, emotional need, and so should be considered an important risk factor when considering gender transition for any patient. However, it is particularly difficult for parents of a young child to seriously contemplate that child's potential as a future parent and grandparent. This makes it all the more critical that the MHP spend substantial and repeated time with parents to help them see the implications of what they are considering. *The percentage of transitioned patients who will become increasingly suicidal as they fully realize the meaning of permanent sterility and the loss of the possibility of being a biological parent has never been studied and is thus unknown.*

90. Sexual-romantic risks associated with transition. After adolescence, transgender individuals find the pool of individuals willing to develop a romantic and intimate relationship with them to be greatly diminished. When a trans person who passes well reveals his or her natal sex, many potential cisgender mates lose interest. When a trans person does not pass well, he discovers that the pool of those interested consists largely of individuals looking for exotic sexual experiences rather than genuinely loving relationships. (Archives Sexual Behavior April 2021) (Levine, *Ethical Concerns*, at 5, 13.) Nor is the problem all on the other side; transgender individuals commonly become strongly narcissistic, unable to give the level of attention to the needs of another that is necessary to sustain a loving relationship. See, S. Levine, *Barriers to Loving: A Clinician's Perspective*, at 40 (Routledge, New York 2013). The percentage of transitioned patients who will become increasingly suicidal as they fully realize the depth of the social isolation experienced by many transgender patients has never been studied and is thus unknown.

91. Social risks associated with delayed puberty. The social and psychological impact of remaining puerile (not growing) for, e.g., three years while one's peers are undergoing puberty, and of undergoing puberty at a substantially older age, have ***not been systematically studied***, although clinical mental health professionals often hear of distress and social awkwardness in those who naturally have a delayed onset of puberty. In my opinion, individuals in whom puberty is delayed multiple years are likely to suffer at least subtle negative psychosocial and self-confidence effects as they stand on the sidelines while their peers are developing the social relationships (and attendant painful social learning experiences) that come with adolescence. (Levine, *Informed Consent*, at 9.) We should recall that puberty introduces sexual desire, changes socialization patterns, and enables teens to enter into early romantic relationships all of which can

lead to maturation, self-confidence, and an understanding of the complexity of partner relationship. *Delaying puberty can reasonably be assumed to increase the adolescent's sense of isolation, otherness, and being an outsider.*

C. Mental health costs or risks

92. One would expect the negative physical and social impacts reviewed above to adversely affect the mental health of individuals who have transitioned. In addition, adult transitioned individuals find that living as the other (or, in a manner that is consistent with the stereotypes of the other as the individual perceives them) is a continual challenge and stressor, and many find that they continue to struggle with a sense of inauthenticity in their transgender identity and bear consequent chronic uneasiness. (Levine, *Informed Consent*, at 9.) In addition, individuals often pin excessive hope in transition, believing that transition will solve what are in fact ordinary social stresses associated with puberty. Thus, transition can result in deflection from mastering personal challenges at the appropriate time, or addressing underlying psychiatric conditions that require treatment. *The percentage of transitioned patients who will become increasingly suicidal due to deflection from mastering personal challenges at the appropriate time, has never been studied and is thus unknown.*

93. Whatever the reason, transgender individuals including transgender youth certainly experience greatly increased rates of mental health problems. I have detailed this above with respect to adults living under a transgender identity. Indeed, Swedish researchers in a long-term study (up to 30 years since Sex Reassignment Surgery (SRS), with a median time since SRS of > 10 years) concluded that ***individuals who have SRS should have postoperative lifelong psychiatric care.*** (Dhejne, Long Term, at 6-7.) With respect to youths a cohort study found that transgender youth had an elevated risk of depression (50.6% vs. 20.6%) and anxiety (26.7% vs.

10.0%); a higher risk of suicidal ideation (31.1% vs. 11.1%), suicide attempts (17.2% vs. 6.1%), and self-harm without lethal intent (16.7% vs. 4.4%) relative to the matched controls; and a significantly greater proportion of transgender youth accessed inpatient mental health care (22.8% vs. 11.1%) and outpatient mental health care (45.6% vs. 16.1%) services.

Regret following transition is not an infrequent phenomenon.

94. The large numbers of children and young adults who have desisted as documented in both group and case studies each represent “regret” over the initial choice in some sense.

95. The phenomenon of desistance or regret experienced *later* than adolescence or young adulthood, or among older transgender individuals, has to my knowledge ***not been quantified or well-studied***. However, it is a real phenomenon. I myself have worked with multiple individuals who have abandoned trans female identity after living in that identity for years, and who would describe their experiences as “regret”.

96. I have seen several Massachusetts inmates and trans individuals in the community abandon their [trans] female identity after several years. (Levine, *Reflections*, at 239.) In the gender clinic which I founded in 1974 and am still part of, we have seen many instances of individuals who claimed a transgender identity for a time, but ultimately changed their minds and reclaimed the gender identity congruent with their sex.

97. More dramatically, a surgical group prominently active in the SRS field has published a report on a series of seven male-to-female patients requesting surgery to transform their surgically constructed female genitalia back to their original male form. See Djordjevic ML, Bizic MR, Duisin D, Bouman MB, Buncamper M. Reversal Surgery in Regretful Male-to-Female Transsexuals After Sex Reassignment Surgery. *J Sex Med*. 2016 Jun;13(6):1000-7. doi: 10.1016/j.jsxm.2016.02.173. Epub 2016 May 4. PMID: 27156012.

98. I noted above an increasingly visible online community of young women who have desisted after claiming a male gender identity at some point during their teen years. Given the rapid increase in the number of girls presenting to gender clinics within the last few years, the phenomena of regret and desistance by young women deserves careful attention and study by MHPs. As reported by one author in 2021, *60,000 testimonies of personal de-transition can be found on the Internet*. See, Pablo Exposito-Campos. A typology of gender detransition and its implications for health care providers J Sex & Marital Therapy 2020 <https://doi.org/10.1080/0092623x.2020.1869126>).

99. Thus, misleading reports of clinical experience, publications that misreport evidence, and the unregulated content of the Internet - many falsely claiming transitions are “easily reversible” — prevent the sobering acceptance of what has previously been asserted for decades — for most all such patients “once a transgendered person, always a transgendered person”, whether referring to a child, adolescent, or adult, male or female.

VI. MEDICAL ETHICS & INFORMED CONSENT

A. The obligation of the mental health professional to enable and obtain informed consent

100. I have reviewed above the knowledge and experience that, in my view, a mental health professional should have before undertaking the responsibility to counsel or treat a child who is experiencing gender dysphoria or transgender identification. The MHP who undertakes this type of responsibility must also be guided by the ethical principles that apply to all health care professionals. One of the oldest and most fundamental principles guiding medical and psychological care—part of the Hippocratic Oath—is that the physician must “do no harm.” This states an ethical responsibility that cannot be delegated to the patient. Physicians themselves must

weigh the risks of treatment against the harm of not treating. If the risks of treatment outweigh the benefits, ethics prohibit the treatment.

101. A distinct ethical responsibility of physicians, when a significant risk exists of adverse consequences to any procedure or therapy, is to ensure that the patient understands and is legally able to consent to these unproven, experimental, high risk, often irreversible, potentially harmful “treatments”, and does consent. To achieve informed consent, the MHP, pediatrician, or other physician must do at least the following:

- a. Must reasonably inform him- or herself regarding the particular situation of his patient;
- b. Must reasonably inform him- or her self concerning the state of knowledge concerning the relevant methodologies and outcomes and the unproven, experimental nature of these “treatments”;
- c. Must honestly inform the patient concerning not only the benefits of treatment, but also the risks and downsides of treatment, and alternative treatments *including no treatment at all as well as the lack of competent scientific study to determine accurate predictions of risks and benefits in this experimental field.*
- d. Must conclude that the patient (or the decision maker, such as parent or healthcare power of attorney) has comprehended what he or she has been told and possesses a cognitive capacity to make a decision based on an adequate understanding of his or her unique life circumstances.

102. Perfunctory “consent” is inadequate to fulfill the professional’s ethical obligation to obtain **truly** informed consent. At the very least, a patient (or parent) considering the life-altering

choice of transition should be helped or indeed required by their clinicians to grapple with four relevant questions:

a. “What benefits do you expect that the consolidation of this identity, gender transition, hormones, or surgery will provide?

b. “What do you understand of the social, educational, vocational, and psychological risks of this identity consolidation and gender role transition?

c. “What do you understand about the common and rare, short- and long-term medical and health risks of hormone and surgical interventions?

d. “What have you considered the nature of your life will be in 10 to 20 years?”
(Levine, *Informed Consent*, at 3.)

e. “Are you fully aware that national science reviews done in England, Sweden, Finland and the US have all noted the lack of credible scientific evidence supporting these experimental treatments? Are you fully aware that the few long-term research studies done in this field support the hypothesis that *patients, in the long run, may be **more harmed than helped** by these experimental “treatments”*?

103. The answers of the patient will enable the professional to make a judgment about how realistic he or she is being. For example, the biological boy who envisions himself as a happy, attractive, socially accepted 21-year-old girl in future college years has probably not been adequately informed of—or has mentally blocked—hard data concerning the mental health and social wellbeing of the transgender population in their 20s, and is failing to consider the material risk that he, as a transgender individual, will not be perceived as attractive to either sex, and the impact that this may have on his future well-being.

104. Most commonly, meaningful engagement with difficult and painful questions such as those above requires a process that will consist of multiple discussions in a psychotherapeutic or counseling context, not merely “disclosure” of facts. In my experience, a too-rapid or too-eager attachment to some outcome is a warning that the patient is not able to tolerate knowledge of the risks and alternative approaches.

105. In my experience, in the area of transgender therapy, rather than the type of information and engagement that I have described, even mental health professionals too often encourage or permit decisions based on a great deal of patient and professional blind optimism about the future that is not grounded in competent, peer reviewed published, reliable-valid scientific research. (Levine, *Ethical Concerns*, at 3-4.) In understanding how the medical and psychological profession is taught how to deal with these patient/ family problems, it is quite clear that knowledge of the scientific limitations of affirmative therapy is not emphasized. Thus, many practitioners passionately, but erroneously, negligently, and unethically, believe that controlled studies with adequate follow-up are the basis for what they have been taught. It is difficult to provide informed consent if the professional is not informed or ideologically driven to be misinformed. Consumer fraud in health care can take place via gross negligence.

B. The interests of the patient, as well as necessary disclosures and consent, must be considered from a life course perspective.

106. The psychiatrist, pediatrician, or psychologist treating a child must have in view not merely (or not even primarily) making the child “happy” now, but making him or her as healthy and happy as possible across the entire trajectory of life, to the extent that is predictable. Certainly, avoiding suicide is one important aspect of a “life course” analysis, and recognizes that “today” is not the only goal. **But as we have demonstrated above, there is no credible scientifically reliable-valid evidence that these experimental treatments actually reduce life-time risk of**

suicide in these patients. There are many more factors across the future decades of the patient's life that also need to be taken into account.

107. Further, in my opinion, a patient can meaningfully be said to know what will make him "happy" over the long term, prior to receiving, understanding, and usually discussing the type of information that I have described above in connection with informed consent. With respect to (most) children who are not equipped to understand, evaluate, and feel the life implications of such information, it is doubtful that there is any meaningful way in which they can be said to "know" what will make them happy over the long term. It is for similar reasons that parents ordinarily make a great many decisions, both large and small, for their young children.

108. Of particular relevance to the life course perspective, when gender-typical men and women undergo elective sterilization, there is a distinct likelihood of eventual regret, in some patients to the point of suicidal despondency. It has been documented that *the younger the age of sterilization, the greater incidence of regret and increased numbers of requests to reverse the sterilized state*. Thus, the medical profession and the courts are quite clear about sterilization: the adult patient must be cognitively able to prudently consider the future consequences in terms of his or her life circumstances. In minors sterilization should be done only to save a life. See A. Burgart et al. (2017), *Ethical Controversy About Hysterectomy for a Minor*, Pediatrics 139(6), DOI:10.1542/peds.2016-3992. This observation has implications for facilitating or even permitting children or adolescents to embark on a path of social transition that within a few years may psychologically steer that individual towards sterilizing chemical or surgical procedures. See S. D. Hillis et al. (1999), *Post-sterilization Regret: Findings from the United States Collaborative Review of Sterilization*, Obstetrics & Gyn 93(6) 889; A. Burgart et al. (2017), *Ethical Controversy About Hysterectomy for a Minor*, Pediatrics 139(6),

DOI:10.1542/peds.2016-3992; K. Curtis et al. (2006), *Regret Following Female Sterilization at a Young Age: A Systematic Review*, *Contraception* 73, 205, DOI:10.1016/j.contraception.2005.08.006; A. Tamar-Mattis (2009), *Exploring Gray Areas in the Law About DSD and Sterilization*, *Endocrine Today*, October ed., <https://www.healio.com/endocrinology/reproduction-androgen-disorders/news/print/endocrine-today/%7Bc6029f85-28ac-43f4-9e7e-0fc897f6313f%7D/exploring-gray-areas-in-the-law-about-dsd-and-sterilization>.

C. Special concerns and ethical rules governing experimentation on patients

109. When psychiatric or medical research is done on subjects the informed consent process is far more rigorous than in ordinary medical and psychiatric procedures. For example, in a recent study of an agent to assist women who are distressed by their lack of sexual desire that I was a part of, the Informed Consent document was 19 pages long.

110. As reported in multiple national science reviews of this field, the absence of competently designed, long-term outcome research studies demonstrating more benefits than damages for gender affirmation interventions (“transitioning treatments”) means that *the claimed therapeutic interventions for these conditions* **are still at a primitive stage of development, and should be considered to be experimental**, rendering adequately informed consent all the more essential, all the more required by ethical and licensing rules-regulations and all the more difficult to obtain. Claims that a civil right is at stake for differently gender identifying people do not change the fact that informed consent is an internationally recognized fundamental human right and that what is proposed is a social and medical experiment. (Levine, *Reflections*, at 241.) (See, Nuremberg Code, Informed Consent Laws in each state, and The Joint Commission on

Accreditation of Healthcare Organizations, or JCAHO [an organization based in the United States that accredits over 20,000 healthcare organizations and programs in the country.] as well as the relevant Health Care Profession Licensing Rules and Regulations in each state.)

111. “Informed consent is often defined as the willing acceptance of a medical intervention by a patient after adequate disclosure by the physician of the A) nature of the intervention, its risks, and benefits, as well as B) the risks and benefits of alternative treatments and C) the risks and benefits of no treatment”.

112. Some of the most tragic chapters in the history of medicine include violations of informed consent and improper experimentation on patients using methods and procedures that have not been tested and validated by methodologically sound science. The infamous Tuskegee experimental studies, the Nazi and Imperial Japanese wartime experimental research on prisoners, the use of lobotomies, the recovered memory therapy movement, the “multiple personality disorder” therapy movement, and the rebirthing therapy movement, all invite comparisons with what is happening to too many gender discordant children and adolescents. In my opinion, health care professionals have ethical, professional, and moral responsibilities to protect the rights of patients and their families to be fully and accurately informed about the risks, benefits, natural history, alternatives, and state of science for the full range of experimental gender affirmation “treatments”. See, <https://www.nobelprize.org/prizes/medicine/1949/moniz/article/> Properly accomplished informed consent is not controversial. Professional ethics codes, licensing rules and regulations, hospital rules and regulations, state and federal laws, and biomedical conventions and declarations all protect patients’ right to informed consent. See, Jonson AR, Siegler M, Winslade, WJ: Clinical Ethics, New York: McGraw Hill, 1998].

D. Ethical principles do not permit using patients as “change agents.”

113. Some advocates assert that various mental health pathologies commonly observed in patients who have transitioned result from societal prejudice, and would not occur if society were different. This is, of course, a hypothesis rather than demonstrated fact, and it is in any case ethically irrelevant to the treatment of an individual patient. If a therapy or life course under consideration for a child will predictably lead to social and family isolation and unemployment later in life given society as it exists, for a MHP or other advisor to recommend or encourage that path nonetheless seems to lose sight of the welfare of the patient. To do so appears to be intentionally using the child as not merely an experiment, but as a change-agent—potentially at great personal cost—rather than seeking the lifetime best interests of that child. (Levine, *Ethical Concerns*, at 9.) It seem audacious of advocates whose primary qualification is being trans oneself to tell parents how their child should be treated.

E. The inability of children to understand major life issues and risks complicates informed consent.

114. Obviously, most children cannot give legally valid consent to a medical procedure. This is not a mere legal technicality. Instead, it is a legal reflection of a reality of human development that is highly relevant to the ethical requirement of informed consent quite apart from law. The argument that the child is consenting to the transition by his happiness ignores the fact just described.

115. Each age group poses different questions about risk comprehension. (Levine, *Informed Consent*, at 3.) While the older patient is perhaps more likely to be formally mental ill and be unrealistic sometimes to the point of being delusional, the young child is chronically unable to comprehend large and complex issues such as the meaning of biological sex, the meaning of gender, and the risks and life implications attendant on social, hormonal, and ultimately surgical transition.

116. In my experience, when clinicians actually attempt to understand patients' motives for the repudiation of their natal gender, the developmental lack of sophistication underlying their reasons can become apparent. What must a 12-year-old, for example, understand about masculinity and femininity that enables the conviction that "I can never be happy in my body?" (Levine, *Ethical Concerns*, at 8.) Obviously, this unavoidable gap in comprehension and ability to foresee must be still larger for younger children.

117. Similarly, one cannot expect a 17-year-old to grasp the complexity of married life with children when 38. One cannot expect a ten-year-old to understand the emotional growth that comes from a first long term love relationship including sexual behavior. One cannot expect a six-year-old to comprehend the changes in his psyche that may come about as the result of puberty. In some States or under some circumstances "mature minors" may be legally empowered to grant consent to certain medical procedures. Arguments have been made that minor adolescents are capable of providing legal informed consent if the physician thinks the patient is reasonable. See Clark & Virani. This wasn't a split-second decision: An empirical ethical analysis of transgender youth capacity, rights, and authority to consent to hormone therapy. Archives of Sexual Behavior published on line 27 January, 2021 doi.org/10.1007/s11673-020-10086-9. Such thinking makes use of the idea that trans people including trans youth are special cases and do not have to follow cultural and scientific truths. This is an argument that I profoundly reject.

118. For this reason, it is my opinion that asking a child whether he or she wishes to transition to living as the opposite sex, or giving large weight to the child's expressed wishes, by no means satisfies the MHP's ethical obligation to obtain informed consent before assisting that child to transition to living as the opposite sex.

119. In light of the profound uncertainties in the field, and the many highly predictable or probable lifetime costs to the child if he or she persists in a transgender identity into adulthood, in my opinion it is not consistent with principles of medical ethics for physicians or other MHPs to suggest that parents should not or have no right to explore possible therapeutic options to assist their child to achieve comfort with the gender corresponding to his or her sex. The use of the label “reparative therapy” or “conversion therapy” by some advocates to lump all such possible therapies together and disparage them does not change this equation. (Levine, *Informed Consent*, at 7.)

120. The transgender clinical arena is growing increasingly uncertain as more attention has been paid to the lack of fundamental studies to support the current widespread fashions of professional recommendations and confirmation bias has been identified in recent highly acclaimed but deeply flawed work. While the general public is now accustomed to reading about trans culture wars, my opinion is that of a clinician who respects scientific methods of ascertaining best treatments. More caution is indicated when the consequences are greater. It has been repeatedly demonstrated in medicine that one size does not fit all. One must reject the idea that if a young person is trans, nothing else matters—the treatment should be immediate affirmation and endocrine support. All must realize that 50 years after trans treatment began to spread across the world, despite more than 10,000 publications, it is not known whether the burgeoning Transgender Treatment Industry is helping or damaging most GD patients.

121. It is my opinion that the scientific community finds the following matters to be uncertain, controversial, or incorrect.

— Gender dysphoria is a serious, physical brain based medical illness that causes suffering that must be treated by hormones and surgery if patients seek such treatments.

— All patients who label themselves as transgendered, regardless of the >120 sub-labels that may be invoked, gender all should be offered the same physical body-changing treatments, if they so desire.

— Hormones and surgery improve the lives of the transgendered in the long run.

— “Above all do no harm” principle can be sidestepped when administering hormones and removing healthy breast and genital tissues in the case of trans persons because it is “medically necessary” —that is, these patients represent a special exception to 2500 years of medical ethics.

-The uncertain long-term adjustments of trans adults, the rates of detransition, disappointment, and chronic depressive, anxiety, and substance abuse disorders do not need to be calculated nor should what is known about high psychiatric morbidity following hormonal and/or surgical treatment should not slow the affirmative treatment policy of trans youth.

--Civil rights considerations are more important than unanswered relevant scientific questions.

XX. SUMMARY OPINIONS:

122. There are no long-term, peer-reviewed published, credible, reliable and valid, research studies documenting or establishing:

- a. The percentage of patients receiving gender transition procedures who are helped by such procedures according to well known criteria.
- b. The percentage of patients receiving gender transition procedures who are harmed by such procedures according to well known criteria.
- c. The reliability and validity of assessing gender identity by relying solely upon the expressed desires of a patient.

d. The mental health outcomes of trans behaving children who are either affirmed or not affirmed in childhood.

e. The percentage of various types of childhood functional challenges and psychiatric diagnoses of trans identified children

f. The percentage of patients whose new trans identity has been created by involvement in social media.

123. The above list of six issues can stimulate new research whose results may shape future trans care. In the meantime, those with gender dysphoria or a trans identity have a right to be more fully informed about what is known as do their physicians. Physicians, psychologists, parents, and patients have a right to be protected from these current experimental, politically tainted, fashionable “treatments”.

124. Informed consent is designed to protect the rights of patients and families, the cognitive and ethical processes of physicians, and the ethical and legal duties of health care institutions. The need for credible, reliable-valid science is also essential to protect each of these entities. The informed consent document for affirmative treatments of youth should specify that up to 88% of children without affirmation will desist (heal naturally without treatment) from their childhood-onset trans preoccupations. Physicians always need to know the patient’s original sex because while gender identity can dramatically change, biological sex and its unique susceptibilities to disease does not.

125. The Transgender Treatment Industry’s policies and advocacies are a niche group of well meaning mental health professionals, endocrinologists, plastic and urological surgeons, and transgendered individuals. Many in their individual professions have differing opinions. They should not be viewed as speaking for all of medicine on these highly controversial issues.

126. Science not politics needs to drive trans care. The medical professions has many tragic examples of when political sensibilities drive medical treatments. When policy is made by voting in the face of low quality science, claims that treatments are evidence-based should be considered misleading and deceptive.

127. No medical, surgical, or psychiatric treatment is invariably successful in producing an agreed upon outcome. In other branches of medicine and psychiatry risks and benefits, outcomes and error rates are better known, far less controversial, and much better proven by credible, reliable-valid scientific research. Error rates for gender affirmation diagnoses, errors rates for predictions of effective vs. harmful affirmation treatments, error rates for increases or decreases in suicidal risk following affirmation treatments, remain unknown. In the field of gender affirmation intervention there has been a rush to treat and a remarkable absence of ethical concern based on obvious scientific limitations as outlined in this report.

128. **Expert Witness Report Methodological Limitations:** My opinions and hypotheses in this matter are — as in all expert witness reports — subject to the limitations of documentary and related evidence, the impossibility of absolute predictions, as well as the limitations of social, biological, and medical science. I have not met with, nor personally interviewed, anyone in this case. As always, I have no expert opinions regarding the veracity of witnesses in this case. I have not yet reviewed all of the evidence in this case and my opinions are subject to change at any time as new information becomes available to me. Only the trier of fact can determine the credibility of witnesses and how scientific research may or may not be related to the specific facts of any particular case. In my opinion, a key role of an expert witness is to help the court, lawyers, parties, and the public understand and apply reliable scientific, technical, and investigative principles, hypotheses, methods, and information. I have transmitted this confidential expert report directly

to attorney John G. Knepper, J.D. for distribution as consistent with the laws of the appropriate jurisdiction for this case.

Pursuant to 28 U.S.C § 1746, I declare under penalty of perjury under the laws of the United

States of America that the foregoing is true and correct.

Date: _____

Signed: _____ Scheduled for Signature 4/29/2021

Stephen B. Levine, M.D.

to attorney John G. Knepper, J.D. for distribution as consistent with the laws of the appropriate jurisdiction for this case.

Pursuant to 28 U.S.C § 1746, I declare under penalty of perjury under the laws of the United

States of America that the foregoing is true and correct.

Date: May 1, 2021

Signed: Stephen B. Levine MD Scheduled for Signature 4/29/2021

Stephen B. Levine, M.D.

Stephen B. Levine, M.D.

Curriculum Vita

Brief Introduction

Dr. Levine is Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine. He is the solo author of four books, *Sex Is Not Simple* in 1989 (translated to German in 1992 and reissued in English in 1997 as *Solving Common Sexual Problems*); *Sexual Life: A clinician's guide* in 1992; *Sexuality in Midlife* in 1998 and *Demystifying Love: Plain talk for the mental health professional* in 2006; *Barriers to Loving: A clinician's perspective* in October 2013. He is the Senior Editor of the first (2003), second (2010) and third (2016) editions of the *Handbook of Clinical Sexuality for Mental Health Professionals*. *Psychotherapeutic Approaches to Sexual Problems: An Essential Guide For Mental Health Professionals* will be published in the fall 2019. He has been teaching, providing clinical care, and writing since 1973 and has generated original research, invited papers, commentaries, chapters, and book reviews. He has served as a journal manuscript and book prospectus reviewer for many years. He was co-director of the Center for Marital and Sexual Health/ Levine, Risen & Associates, Inc. in Beachwood, Ohio from 1992-2017. He and two colleagues received a lifetime achievement Masters and Johnson's Award from the Society for Sex Therapy and Research in March 2005.

Personal Information

Date of birth 1/14/42

Medical license no. Ohio 35-03-0234-L

Board Certification 6/76 American Board of Neurology and Psychiatry

Education

1963 BA Washington and Jefferson College

1967 MD Case Western Reserve University School of Medicine

1967-68 internship in Internal Medicine University Hospitals of Cleveland

1968-70 Research associate, National Institute of Arthritis and Metabolic Diseases, Epidemiology Field Studies Unit, Phoenix, Arizona, United States Public Health Service

1970-73 Psychiatric Residency, University Hospitals of Cleveland

1974-77 Robert Wood Johnson Foundation Clinical Scholar

Appointments at Case Western Reserve University School of Medicine

1973 - Assistant Professor of Psychiatry

1979 - Associate Professor

1982 - Tenure

1985 - Full Professor

1993 - Clinical Professor

Honors

Summa Cum Laude, Washington & Jefferson

Teaching Excellence Award - 1990 and 2010 (residency program)

Visiting Professorships:

- Stanford University-Pfizer Professorship program (3 days) - 1995
- St. Elizabeth's Hospital, Washington, DC - 1998
- St. Elizabeth's Hospital, Washington, DC - 2002

Named to America's Top Doctors consecutively since 2001

Invitations to present various Grand Rounds at Departments of Psychiatry and Continuing Education Lectures and Workshops

Masters and Johnson Lifetime Achievement Award from the Society of Sex Therapy and Research, April 2005 along with Candace Risen and Stanley Althof

2006 SSTAR Book Award for The Handbook of Clinical Sexuality for Mental Health Professionals: Exceptional Merit

2018 - Albert Marquis Lifetime Achievement Award from Marquis Who's Who. (excelling in one's field for at least twenty years)

Professional Societies

1971 - American Psychiatric Association; fellow

2005 - American Psychiatric Association - **Distinguished Life Fellow**

1973 - Cleveland Psychiatric Society

1973 - Cleveland Medical Library Association

- 1985 - Life Fellow
- 2003 - Distinguished Life Fellow

1974 - Society for Sex Therapy and Research

- 1987-89 - President

1983 - International Academy of Sex Research

1983 - Harry Benjamin International Gender Dysphoria Association

- 1997-98 - Chairman, Standards of Care Committee

1994-99 - Society for Scientific Study of Sex

Community Boards

1999-2002 - Case Western Reserve University Medical Alumni Association

1996-2001 - Bellefaire Jewish Children's Bureau

1999-2001 - Physicians' Advisory Committee, The Gathering Place (cancer rehabilitation)

Editorial Boards

1978-80 Book Review Editor Journal Sex and Marital Therapy

Manuscript Reviewer for:

- Archives of Sexual Behavior
- Annals of Internal Medicine
- British Journal of Obstetrics and Gynecology
- JAMA
- Diabetes Care
- American Journal of Psychiatry
- Maturitas
- Psychosomatic Medicine
- Sexuality and Disability
- Journal of Nervous and Mental Diseases
- Journal of Neuropsychiatry and Clinical Neurosciences
- Neurology
- Journal Sex and Marital Therapy
- Journal Sex Education and Therapy
- Social Behavior and Personality: an international journal (New Zealand)
- International Journal of Psychoanalysis
- International Journal of Transgenderism
- Journal of Urology
- Journal of Sexual Medicine
- Current Psychiatry
- International Journal of Impotence Research
- Postgraduate medical journal
- Academic Psychiatry

Prospectus Reviewer for:

- Guilford
- Oxford University Press

- Brunner/Routledge
- Routledge

Administrative Responsibilities

Co-director, Center for Marital and Sexual Health/ Levine, Risen & Associates, Inc. until June 30, 2017

Principal Investigator of approximately 70 separate studies involving pharmacological interventions for sexual dysfunction since 1989.

Co-leader of case conferences at DELRLLC.com

Recent Expert Witness Appearances

US District Court, Judge Mark L. Wolf's witness in Michelle Kosilek vs. Massachusetts Dept of Corrections et al. case (transsexual issue) in Boston 2007

Deposition in the Battista vs. Massachusetts Dept of Corrections case (transsexual issue) in Cleveland October 2009

Witness for Massachusetts Dept. of Corrections in their defense of a lawsuit brought by prisoner Katheena Soneeya. March 22, 2011 Deposition in Boston and October 2018 in Cleveland

Witness for State of Florida vs. Reyne Keohane July 2017

Expert testimony by deposition and at trial in *In the Interests of the Younger Children*, Dallas, TX, 2019.

Consultancy

Massachusetts Department of Corrections - evaluation of 12 transsexual prisoners and the development of a Gender Identity Disorders Program for the state prison system. Monthly consultation with the GID treatment team since February 2009 and the GID policy committee since February 2010

California Department of Corrections and Rehabilitation; 2012-2015; education, inmate evaluation, commentary on inmate circumstances, suggestions on future policies

Virginia Department of Corrections - evaluation of an inmate

New Jersey Department of Corrections - evaluation of an inmate

Idaho Department of Corrections - workshop 2016

Grant Support/Research Studies

TAP - studies of Apomorphine sublingual in treatment of erectile dysfunction

Pfizer - Sertraline for premature ejaculation

Pfizer - Viagra and depression; Viagra and female sexual dysfunction; Viagra as a treatment for SSRI-induced erectile dysfunction

NIH - Systemic lupus erythematosus and sexuality in women

Sihler Mental Health Foundation

- Program for Professionals
- Setting up of Center for Marital and Sexual Health
- Clomipramine and Premature ejaculation
- Follow-up study of clergy accused of sexual impropriety
- Establishment of services for women with breast cancer

Alza - controlled study of a novel SSRI for rapid ejaculation

Pfizer - Viagra and self-esteem

Pfizer - double-blind placebo control studies of a compound for premature ejaculation

Johnson & Johnson - controlled studies of Dapoxetine for rapid ejaculation

Proctor and Gamble - multiple studies to test testosterone patch for post menopausal sexual dysfunction for women on and off estrogen replacement

Lilly-Icos - study of Cialis for erectile dysfunction

VIVUS - study for premenopausal women with FSAD

Palatin Technologies - studies of bremelanotide in female sexual dysfunction—first intranasal then subcutaneous administration

Medtap - interview validation questionnaire studies

HRA - quantitative debriefing study for Female partners of men with premature ejaculation, Validation of a New Distress Measure for FSD,

Boehringer-Ingelheim - double blind and open label studies of a prosexual agent for hypoactive female sexual desire disorder

Biosante - studies of testosterone gel administration for post menopausal women with HSDD

J&J - a single-blind, multi-center, in home use study to evaluate sexual enhancement effects of a product in females.

UBC - Content validity study of an electronic FSEP-R and FSDS-DAO and usability of study PRO measures in premenopausal women with FSAD, HSDD or Mixed FSAD/HSDD

National registry trial for women with HSDD

Endoceutics - two studies of DHEA for vaginal atrophy and dryness in post menopausal women

Palatin - study of SQ Bremelanotide for HSDD and FSAD

Trimel - a double-blind, placebo controlled study for women with acquired female orgasmic disorder.

S1 Biopharma - a phase 1-B non-blinded study of safety, tolerability and efficacy of Lorexys in premenopausal women with HSDD

HRA - qualitative and cognitive interview study for men experiencing PE

Publications

A) Books

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- 7) Demystifying Love: Plain Talk For The Mental Health Professional. Routledge, New York, 2006
- 8) Senior editor, (Candace B. Risen and Stanley E. Althof, Associate editors), Handbook of Clinical Sexuality for Mental Health Professionals. 2nd edition Routledge, New York, 2010. See review by Pega Ren, JSex&Marital Therapy
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B) Research and Invited Papers

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 - (c) Do men like women to be sexually assertive? 1977;11:44
 - (d) Absence of sexual desire in women: Do some women never experience sexual desire? Is this possibility genetically determined? 1977; 11:31
 - (e) Barriers to the attainment of ejaculatory control. 1979; 13:32-56.
 - (f) Commentary on sexual revenge.1979;13:19-21
 - (g) Prosthesis for psychogenic impotence? 1979;13:7
 - (h) Habits that infuriate mates. 1980;14:8-19
 - (i) Greenberger-Englander, Levine SB. Is an enema an erotic equivalent?1981; 15:116
 - (j) Ford AB, Levine SB. Sexual Behavior and the Chronically Ill Patients. 1982; 16:138-150
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